TO COMPARE THE ROLE OF CONVENTIONAL ASSISTIVE DEVICES AND PROSTHESIS IN REDUCING DYNAMIC PLANTAR PRESSURES OF THE PRECIOUS LIMB POST TRANSTIBIAL AMPUTATION DURING GAIT IN DIABETIC PATIENTS : AN OBSERVATIONAL STUDY

A dissertation submitted in partial fulfillment of the requirements of MS General Surgery Branch I examination of the Tamil Nadu Dr. MGR university Chennai to be held in 2019.

Declaration

This is to certify that the dissertation titled “ To compare the role of conventional assistive devices (orthotics) and prosthesis in reducing dynamic plantar pressures of the precious limb, post transtibial amputation, during gait in Diabetic patients” which is submitted by me in partial fulfillment towards M.S. Branch I (General surgery) examination of the Tamil Nadu Dr MGR University, Chennai, to be held in 2019 comprises only my original work and the due acknowledgement has been made in text to all materials used.

CANDIDATE

Dr. JALAZ JOEZER RAHMI

Regn. No. 221611456

PG Registrar, Department of General Surgery

Christian Medical College, Vellore -632004, India

Guide: **Head of Department:** **Principal:**

Department of General Surgery

Acknowledgements

I would like to thank the following people who have guided me during this project.

Firstly, I would like to thank my advisor, Dr. John C. Muthusami, under whose guidance, I initiated this study. His constant criticism was valuable during the designing of this study.

I would also like to thank my advisors, Dr. Cecil T. Thomas and Suresh D. whose recommendations and instructions helped me to assemble this final dissertation effectively.

My study would have been incomplete without the patients, who took great pains to volunteer for the study and provided valuable insight towards rehabilitation of other such patients.

I would like to thank Dr. George, and Dr. Riddhi, for allowing me to recruit patients and conduct the study in their respective departments.

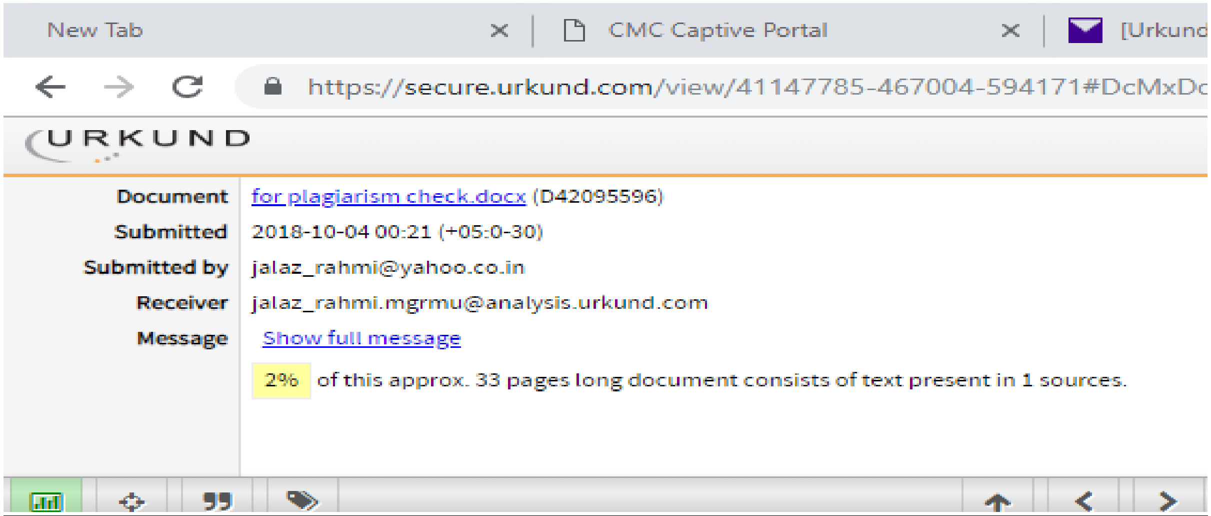
I would like to thank my family for the constant encouragement and support.

I would like to thank Mr. Bijesh, who worked meticulously and provided significant support towards the analysis and completion of this project.

I would like to thank Sahil, whose technical expertise aided in the completion of the project.

In the end, I would like to thank God Almighty, who gives us the wisdom and discernment to carry out all that we do.

ANTI-PLAGIARISM CERTIFICATE



This is to certify that the dissertation work titled " **To compare the role of conventional assistive devices and prosthesis in reducing dynamic plantar pressures of the precious limb post transtibial amputation during gait in Diabetic patients**" of the candidate **Jalaz Joezer Rahmi** with registration number **221611456** for the award of Masters in the branch of General Surgery. I personally verified the urkund.com website for the purpose of plagiarism check. I found that the uploaded thesis file from Introduction to Conclusion pages and results shows **2** percentage of plagiarism in the dissertation.

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Director, Christian Counseling Center,
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Dr. Anna Benjamin Pulimood, M.B.B.S., MD., Ph.D.,
Chairperson, Research Committee & Principal

Dr. Biju George, M.B.B.S., MD., DM.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

December 13, 2016.

Dr. Jalaz Joezer Rahmi,
PG Registrar,
Department of General Surgery,
Christian Medical College,
Vellore – 632 002.

Sub: **Fluid Research Grant NEW PROPOSAL:**
To compare the role of conventional assistive devices (orthotics) and prosthesis in reducing dynamic plantar pressures of precious limb, post transtibial amputation, during gait in diabetic patients.
Dr. Jalaz Joezer Rahmi, Employment No.29459, PG Registrar, Dr. John C. Muthusami, Emloyment No. 12899, Dr. Vasanth Mark Samuel, Associate Professor, Department of General Surgery Unit I, Dr Nihal Thomas , Professor, Endocrinology, Dr George Tharion, Professor, Physical Medical Rehabilitation, Dr Suresh Devaashayam, Professor, Bioengineering.

Ref: IRB Min. No. 10428 dated 05.12.2016

Dear Dr. Jalaz Joezer Rahmi,

The Institutional Review Board **(Blue**, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project titled "To compare the role of conventional assistive devices (orthotics) and prosthesis in reducing dynamic plantar pressures of precious limb, post transtibial amputation, during gait in diabetic patients" on December 05th 2016. I am quoting below the minutes of the meeting.

The Committee raises the following queries:

1. Who will do the evaluation and where will it be done
2. Temperature testing is not part of sensory assessment -
3. Starting date needs to be changed
4. 5 different fonts in the write up – needs to be uniform
5. Summary of the proposal – is not a summary
6. are you doing a pre and post assessment before the prosthesis
7. Sample size calculation – needs reference and the difference in the mean
8. Statistical methods – need to mention what statistics will be used for calculation not sample size calculation.

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Tel: 0416 – 2284294. 2284202 Fax: 0416 – 2262788, 2284481 E-mail: research@cmcvellore.ac.in

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CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA

Dr. B.J. Prashantham, M.A., M.A., Dr. Min (Clinical)
Director, Christian Counseling Center,
Chairperson, Ethics Committee.

Dr. Anna Benjamin Pulimood, M.B.B.S., MD., Ph.D.,
Chairperson, Research Committee & Principal

Dr. Biju George, M.B.B.S., MD., DM.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

9. Make the budget more accurate
10. Signatures missing

Drs. Jalaz Joezer Rahmi and John C Muthusami were present during the presentation of the proposal and satisfactorily responded to the queries raised by the Members. After discussion, it was resolved to **ACCEPT the proposal after receiving the suggested modifications and answers to the queries.**

Note:
1. Kindly HIGHLIGHT the modifications in the revised proposal.
2. Keep a covering letter and point out the answer to the queries.
3. Reply to the queries should be submitted within 3 months duration from the time of the thesis/ protocol presentation, if not the thesis/protocol have to be resubmitted to the IRB.
4. The checklist has to be sent along with the answers to queries.

Email the details to research@cmcvellore.ac.in and send a hard copy through internal dispatch to Dr. Biju George, Addl. Vice-Principal (Research), Principal's Office, CMC.

Yours sincerely,

Dr. Biju George
Secretary (Ethics Committee)
Institutional Review Board.

Dr. BIJU GEORGE
MBBS., MD., DM
SECRETARY - (ETHICS COMMITTEE)
Institutional Review Board,
Christian Medical College, Vellore - 632 002.

Cc: Dr. John C Muthusamy, Department of General Surgery, CMC Vellore.

Ethics Committee Blue, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002
Tel: 0416 – 2284294. 2284202 Fax: 0416 – 2262788, 2284481 E-mail: research@cmcvellore.ac.in

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January 28, 2017

Dr. Jalaz Joezer Rahmi,
PG Registrar,
Department of General Surgery 1,
Christian Medical College,
Vellore - 632 004.

Sub: **Fluid Research Grant NEW PROPOSAL:**
To compare the role of conventional assistive devices (orthotics) and prosthesis in reducing dynamic plantar pressures of precious limb, post transtibial amputation, during gait in diabetic patients.
Dr. Jalaz Joezer Rahmi, Employment No.29459, PG Registrar, Dr. John C. Muthusami, Emloyment No. 12899, Dr. Vasanth Mark Samuel, Associate Professor, Department of General Surgery Unit I, Dr Nihal Thomas , Professor, Endocrinology, Dr George Tharion, Professor, Physical Medical Rehabilitation, Dr Suresh Devaashayam, Professor, Bioengineering

Ref: IRB Min No: 10428 [OBSERVE] dated 05.12.2016

Dear Dr. Jalaz Joezer Rahmi,

I enclose the following documents:-

1. Institutional Review Board approval 2. Agreement

Could you please sign the agreement and send it to Dr. Biju George, Addl. Vice Principal (Research), so that the grant money can be released.

With best wishes,

Dr. Biju George
Secretary (Ethics Committee)
Institutional Review Board

Dr. BIJU GEORGE
MBBS., MD., DM.
SECRETARY - (ETHICS COMMITTEE)
Institutional Review Board,
Christian Medical College, Vellore - 632 002.

Cc: Dr. John C. Muthusami, Dept. of General Surgery Unit I, CMC, Vellore

Ethics Committee Blue, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002
Tel: 0416 – 2284294. 2284202 Fax: 0416 – 2262788, 2284481 E-mail: research@cmcvellore.ac.in

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Ref: IRB Min No: 10428 [OBSERVE] dated 05.12.2016

Dear Dr. Jalaz Joezer Rahmi,

The Institutional Review Board (Blue, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project titled "To compare the role of conventional assistive devices (orthotics) and prosthesis in reducing dynamic plantar pressures of precious limb, post transtibial amputation, during gait in diabetic patients" on December 05th 2016.

The Committee reviewed the following documents:

1. IRB Application format
2. Cvs of Drs. Jalaz, Suresh Devasahayam, John C MuthuSwami, George Tharion and Vasanth M.
3. Consent for Participation and Informed Consent Form.
4. No. of documents 1- 3

The following Institutional Review Board (Blue, Research & Ethics Committee) members were present at the meeting held on December 05th 2016 in the BRTC Conference Room, Christian Medical College, Bagayam, Vellore 632002.

Ethics Committee Blue, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002
Tel: 0416 – 2284294, 2284202 Fax: 0416 – 2262788, 2284481 E-mail: research@cmcvellore.ac.in

Name	Qualification	Designation	Affiliation
Dr. Biju George	MBBS, MD, DM	Professor, Haematology, Research), Additional Vice Principal , Deputy Chairperson (Research Committee), Member Secretary (Ethics Committee), IRB, CMC,Vellore	Internal, Clinician
Dr. B. J. Prashantham	MA(Counseling Psychology), MA (Theology), Dr. Min (Clinical Counselling)	Chairperson, Ethics Committee, IRB. Director, Christian Counseling Centre, Vellore	External, Social Scientist
Dr. Ratna Prabha	MBBS, MD (Pharma)	Associate Professor, Clinical Pharmacology, CMC, Vellore	Internal, Pharmacologist
Dr. Rekha Pai	BSc, MSc, PhD	Associate Professor, Pathology, CMC, Vellore	Internal,Basic Medical Scientist
Rev. Joseph Devaraj	BSc, BD	Chaplaincy Department, CMC, Vellore	Internal, Social Scientist
Mr. C. Sampath	BSc, BL	Advocate, Vellore	External, Legal Expert
Dr. Simon Pavamani	MBBS, MD	Professor, Radiotherapy, CMC, Vellore	Internal, Clinician
Dr. Rajesh Kannangai	MD, PhD.	Professor, Clinical Virology, CMC, Vellore	Internal, Clinician
Ms. Grace Rebekha	M.Sc., (Biostatistics)	Lecturer, Biostatistics, CMC, Vellore	Internal, Statistician
Mrs. Pattabiraman	BSc, DSSA	Social Worker, Vellore	External, Lay Person
Dr. Anuradha Rose	MBBS, MD, MHSC (Bioethics)	Associate Professor, Community Health, CMC, Vellore	Internal, Clinician
Dr. Balamugesh	MBBS, MD(Int Med), DM, FCCP (USA)	Professor, Pulmonary Medicine, CMC, Vellore	Internal, Clinician

Ethics Committee Blue, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002
Tel: 0416 – 2284294. 2284202 Fax: 0416 – 2262788, 2284481 E-mail: research@cmcvellore.ac.in

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CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA

Dr. B.J. Prashantham, M.A., M.A., Dr. Min (Clinical)
Director, Christian Counseling Center,
Chairperson, Ethics Committee.

Dr. Anna Benjamin Pulimood, M.B.B.S., MD., Ph.D.,
Chairperson, Research Committee & Principal

Dr. Biju George, M.B.B.S., MD., DM.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

Dr. Santhanam Sridhar	MBBS, DCH, DNB	Professor, Neonatology, CMC, Vellore	Internal, Clinician
Mrs. Emily Daniel	MSc Nursing	Professor, Medical Surgical Nursing, CMC, Vellore	Internal, Nurse
Dr. Mathew Joseph	MBBS, MCH	Professor, Neurosurgery, CMC, Vellore	Internal, Clinician

We approve the project to be conducted as presented.

Kindly provide the total number of patients enrolled in your study and the total number of withdrawals for the study entitled: "To compare the role of conventional assistive devices (orthotics) and prosthesis in reducing dynamic plantar pressures of precious limb, post transtibial amputation, during gait in diabetic patients" on a monthly basis. Please send copies of this to the Research Office (research@cmcvellore.ac.in).

Fluid Grant Allocation:
A sum of 1,00,000/- INR (Rupees One Lakh Only) will be granted for 2 years. 50,000/- INR (Rupees Fifty Thousand only) will be granted for 12 months as an Ist Installment. The rest of the 50,000/- INR (Rupees Fifty Thousand only) each will be released at the end of the first year as 2 nd Installment..

Yours sincerely,

Dr. Biju George
Secretary (Ethics Committee)
Institutional Review Board

Dr. BIJU GEORGE
MBBS., MD., DM.
SECRETARY - (ETHICS COMMITTEE)
Institutional Review Board,
Christian Medical College, Vellore - 632 002.

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Ethics Committee Blue, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002
Tel: 0416 – 2284294, 2284202 Fax: 0416 – 2262788, 2284481 E-mail: research@cmcvellore.ac.in

ABSTRACT

Role of conventional assistive devices versus prosthesis in reducing dynamic plantar pressures during gait in Diabetic patients post trans-tibial amputation.

Aims and objectives

Aim:

To compare the role of conventional assistive devices and prosthesis in reducing dynamic plantar pressures on precious limb, post transtibial amputation, during gait in diabetic patients.

Primary objective:

To compare plantar pressure points during gait in the precious limb while using axillary crutches or walkers and while using prosthesis.

Secondary objective:

To identify areas of high pressures and suggest appropriate modifications in the footwear or prosthesis so as to reduce pressure at those points and prevent ulcers and subsequent amputations.

Methods:

This was designed as an observational study, approved by the institutional review Board with a financial grant for the same. A total of 51 Diabetic patients, who had undergone emergency or elective below knee amputation, and had been rehabilitated with a below knee prosthesis were recruited for the study. The precious limb was the main focus of the study and dynamic plantar pressures were measured with and without the prosthesis once the patient ambulated. The tools used to measure plantar pressures were an in-house device, in the form of pressure sensing probes fitted into an insole which could be easily inserted into the patient footwear. The device was connected to a computer which showed waveforms suggestive of the plantar pressure distribution. The following parameters were also assessed:

a) Sensory testing assessment
b) Routine diabetic profile in the form of glycosylated hemoglobin
c) Height, weight and Body Mass Index.

Results:

The dynamic plantar pressures were lower with prosthesis as compared to without prosthesis. The mean pressure difference was found to be about 6.8 kiloPascals.

($p < 0.001$)

The highest pressure difference amongst individual plantar points was found to be at the first metatarsal, with a mean difference of 24.3 kiloPascals. ($p < 0.001$)

The forefoot to rear-foot ratio was also found to be significant ($p < 0.001$) with prosthesis (0.9) as compared to without prosthesis (0.4). Body Mass Index and glycemic control did not contribute to pressure changes during gait while using prosthesis.

Hence this proves our hypothesis, that prosthesis are more effective in reduction of plantar pressures in the precious limb in Diabetics during gait, as compared to orthotic devices like crutches or walkers. Hence, it is recommended that Diabetic amputees be encouraged to undergo pre-prosthetic training and eventually use prosthesis for ambulation.

Also, even though the patient may have been rehabilitated with a prosthesis, it is imperative that regular inspection of the precious foot is done. This said, the device can be used as a standard, economic, diagnostic and therapeutic tool in detecting early pressure changes and that plantar pressure distribution become a routine part during diabetic foot assessment.

Contents

INTRODUCTION

Diabetes has been described as an epidemic by the World Health Organization with lower limb amputations resulting as one of its most devastating complications. After a unilateral major lower limb amputation, the likelihood of a contralateral amputation is very high according to current literature. A serious infection is often precipitated by ulcers that form due to trauma or areas of high plantar pressure.

In our clinical setting, patients who have undergone a lower limb amputation may use either an orthosis (crutches or walkers) or prosthesis to ambulate. There is no published data comparing both modalities with regards to plantar pressures in the contralateral limb. The study aims at determining the plantar pressure distribution while walking with either prosthesis or orthosis and determining which is a better mode of rehabilitation in offloading the precious limb.

AIMS AND OBJECTIVES

To assess the role of conventional assistive devices (orthotics) and prosthesis in reducing dynamic plantar pressures on precious limb.

1) Primary objective: to compare the plantar pressure distribution on the contralateral limb while using orthotics and prosthesis while walking in patients who have undergone transtibial amputation and have been rehabilitated.
2) Secondary objective: to identify the high-pressure areas on the foot while walking for appropriate modifications in the prosthesis to reduce the plantar pressures on that foot.

JUSTIFICATION OF THE STUDY

India currently has the highest prevalence of Diabetes amongst the world population, with currently 62 million people diagnosed with Diabetes Mellitus, which is predicted to increase to 120.9 million by 2030.(1) Individuals with Diabetes have a 30-fold higher lifetime risk of undergoing lower extremity amputation as compared to those without Diabetes, the most important factors being development of foot ulcers due to neuropathy and trauma. Various studies in India show that major amputations range from 10.5% to 48%. Suliman et al showed that below knee amputations were the commonest major amputations performed(2). There is a 30% higher chance of this population undergoing an amputation in the precious limb 3 years after the first surgery. Hence the need for assessing plantar pressures.

LITERATURE REVIEW

Epidemiology and causes of lower limb amputations:

An Estimated 10% of the world population faces some form of disability(3). While its definition varies, it can overall be referred to as loss of health, which includes mobility, cognition, hearing and vision(4).

Amputations contribute to this and is one of the most ancient forms of surgical treatment, dating back to the 16th century. Ambroise Pare has been recognized as the earliest surgeon in usage of ligatures and prostheses in relation to amputations. Increase in the life span, improvements in transportation methods and development of mechanical civilization have been a major factor leading to increase in number of amputees(5).

Amputations can occur in the aftermath of major disasters, natural calamities, war and road traffic accidents, workplace injuries, industrial accidents or sports injuries. Trauma accounts as a leading cause for lower limb amputations in developing countries followed by arterio-occlusive diseases. This can be due to Diabetes, hypertension, dyslipidemia or thrombangitis obliterans. Tumors account for 0.8% of total amputations. The picture is different in developed countries where peripheral vascular diseases accounted for majority of the amputations as compared to trauma(6). This has been influenced by industrialization, mechanization, transportation systems and medical care available. Also, lower incidence of obesity and resultant Diabetes in our population as compared to developed countries contributes to this.

Incidence and prevalence

The incidence and prevalence are difficult to determine and varies from country to country. Also, data pertaining to true incidence and prevalence is still lacking as majority of the patients presenting to the outpatient department with Diabetic foot ulcers are not accounted for.

Of the few comprehensive reviews, one by Reiber et al, stated that chronic ulcers were present in 2.7% of all hospitalizations associated with Diabetes. It was mostly found in individuals aged 45-64 years with higher predilection for men and longer duration of hospital stay due to the presence of an ulcer(7).

In elderly patients, trauma was one of the commonest causes of major amputations, with a male predeliction(8). The incidence of major amputations was greater than that of minor amputations(9).

Diabetes and lower limb amputations

India is currently the Diabetic capital of the world with more than 35 million people affected by Diabetes, and this number is expected to increase to more than 80 million by 2030(1). In developing countries like India, Diabetic foot complications are one of the commonest. Amputations among Diabetics is more common than non-diabetics, and in all these cases, the amputation is preceded by a foot ulcer. Individuals with Diabetes have a fifteen fold times more risk of lower extremity amputations as compared to non-Diabetics. (10)

The development of a foot ulcer is considered to be a result of the combination of infection, peripheral neuropathy, ischemia and poor foot hygiene(11). Lower extremity amputation is 12.5 to 31.6 times more in a Diabetic person as compared to a non-diabetic(12). The most important cause of major amputations in India is trauma, followed by Diabetes(9). In a multi-centric study done in India, the most common cause leading to amputations was found to be infections. Amongst those undergoing amputations, trans-tibial was the commonest, accounting for 50% of the major lower amputations, followed by trans-femoral in 11.9% cases.

Upto 30 percent of the amputee population undergo contralateral lower limb amputation within 3 years of the initial amputation. After a major lower extremity amputation, 5.7% at 1 year and 11.5% at 5 years undergo amputation of the contralateral lower limb. After a minor lower limb amputation, 3.2% at 1 year and 8.4% at 5 years have a contralateral lower limb amputation. Also, for those with minor lower extremity amputations, 10.5% and 14.2% have ipsilateral major amputations at 1 and 5 years respectively. (13)

In India, the mean age of amputation in our population is 60 years as compared to 75 years in the western population. The mortality following an amputation is up to 15% in the Indian population as compared to 50% in the western population. The higher rate of mortality in the west is accounted for due to older age, and presence of atherosclerosis and multi-system involvement at the time of presentation. The rate of contralateral lower limb amputations in India is 8.92% within two years of the initial amputation. Such a high rate of contralateral limb loss in diabetics needs to be closely addressed. Diabetes mellitus has been termed as a global epidemic by WHO and measures need to be taken by rehabilitation centers and institutes to prevent contralateral limb loss. The population estimated to be affected by diabetes will reach 300 million by 2025. (14) About 50% of the patients who have been affected by Diabetes mellitus for more than 20 years are prone to developing peripheral neuropathy. (15) Diabetic neuropathy is an important complication, affecting the central, peripheral and autonomic nervous systems and causing impairment, in that order, resulting in foot injuries, chronic non healing ulcers and eventually amputations.(16) It begins as a progressive loss in tactile sensation, which is the followed by loss of pain, followed by loss of thermal sensitivity and subsequently proprioception, and is termed as restrictive neuropathy at this point. Motor neuropathy follows, and subsequently there is muscle atrophy of the intrinsic muscles of the foot resulting in foot deformities. Autonomic neuropathy leads to impairment of joint mobility. It also impairs the sympathetic and parasympathetic innervations controlling the sweat glands of the foot, thereby resulting in decreased sweat production, increased dryness and fissuring of the skin which predisposes to ulcer formation.(17)

Pathophysiology of foot ulcers in Diabetic patients

About 60% of foot ulcers are found as a result of underlying neuropathy. (18) Many in-vitro and animal studies have been conducted which have shown the development of neuropathy in affected patients as a result of hyperglycemia-induced metabolic abnormalities.(19)

One commonly described mechanism of action is the polyol pathway. In a state of hyperglycemia, increased activity of the enzymes sorbitol dehydrogenase and aldose reductase results in the conversion of intracellular glucose to sorbitol and fructose. Increase in the levels of these metabolic components causes a decrease in the production of nerve cell myoinositol, synthesis of which is important for normal neuron conduction. Also, chemical conversion of glucose causes depletion in the levels of nicotinamide adenine dinucleotide phosphate levels, which are important for removal of reactive oxygen species and synthesis of nitric oxide required for vasodilatation. This results in oxidative stress and damage to the neurons and increase vasoconstriction in the vasa nervosum leading to nerve cell ischemia, and eventually death. There may also be inappropriate activation of protein kinase C, which may aggravate nerve cell dysfunction and ischemia. (20)

Neuropathy involves the motor, sensory and autonomic components. During motor involvement, there is damage to the innervation to the intrinsic muscles of the foot. This results in an imbalance in the flexor and extensor activity of the muscles, resulting in a change in the spatial orientation of the bones of the foot. This causes anatomic foot deformities resulting in abnormal bony prominences and pressure points which are prone to shear stresses during ambulation and weight-bearing and lead to skin breakdown and ulceration.

Autonomic neuropathy causes a decrease in the functionality of the sebaceous glands of the foot which are responsible for moisturization of the skin over the foot. The skin becomes dry and increasingly susceptible to forming cracks and calluses, which may subsequently progress to ulcer formation and development of infections.

Loss of sensation, and sensory reflexes is the most debilitating effect of diabetic neuropathy, wherein, patients are unable to perceive pain due to constant trauma to their lower extremities at the affected site. As a result, there is a loss of protective reflexes and the patient may continue to apply repetitive pressure at the site during normal ambulation and may notice the trauma at the site only at a point where it has progressed to form an ulcer. (18)

Presence of a concomitant peripheral arterial occlusive disease plays an important role in the development of diabetic foot ulcers in about 50% cases. It commonly affects the tibial and peroneal arteries of the lower limb. Hyperglycemia induces endothelial dysfunction in these vessels, resulting in an imbalance in the ratio of vasoconstrictors and vasodilators, resulting in a decrease in the latter. There is an increased production of Thromboxane A2, which is a potent vasoconstrictor and platelet aggregator, resulting in thrombus formation and vessel occlusion. Added to this, smoking, hypertension and dyslipidemia, which is seen very commonly in diabetic patients, has a cumulative effect in arterial occlusion and results in increased risk of ulceration in diabetic patients. (21)

Applied anatomy of the foot

The medial and lateral longitudinal arches and the transverse arches play an important role in ambulation.

Medial longitudinal arch

This is formed posteriorly by the heel and anteriorly by the medial three metatarsophalangeal joints. It is made up of the calcaneus, the talar head, the navicular, the three cuneiforms, and the medial three metatarsals. The posterior pillar is formed by the posterior part of the inferior calcaneal surface and the anterior pillar is formed by the three metatarsal heads. The bones however, contribute very little to the arch and is more significantly stabilized by the ligaments. The plantar aponeurosis is an important support for these arches and behaves as a tie beam for them. Dorsiflexion, especially of the great toe, brings the two pillars together and increases the height of the arch.

The spring ligament is the other important structure, which supports the head of the talus. The navicular and calcaneum can separate if this ligament does not function. As a result, the talar head, which is the highest point in the arch, descends, thereby resulting in a flat-foot deformity. The talocalcaneal ligaments and the anterior fibers of the deltoid ligament also play a role in stabilizing the arch.

Muscles also play an important role in maintenance of the medial longitudinal arch. Most important of these being the flexor hallucis longus. Flexor digitorum longus, abductor hallucis, and medial half of the flexor digitorum brevis also contribute to a lesser extent.

Tibialis posterior causes inversion and adduction of the foot and thus helps in elevation of the medial border of the foot. The failure of the tibialis posterior tendon manifests as the collapse of the medial longitudinal arch.

Lateral longitudinal arch

This arch is less pronounced as compared to the medial longitudinal arch. It is formed by the calcaneus, cuboid, and the lateral two metatarsals. The pillars are formed by the metatarsal heads anteriorly and the calcaneus posteriorly. Ligaments play a more important role in the stabilization of the arch, mainly the lateral part of the plantar aponeurosis and the short plantar ligaments. The fibularis longus tendon plays the main role in maintenance of the lateral arch. This is also done by the fibers of the flexor digitorum longus, abductor digiti minimi, and fibers of the fibularis brevis and tertius.

Transverse arch

The five metatarsals, the cuneiforms and the cuboid bone constitute the transverse arch. The intermediate and lateral cuneiforms are wedge shaped and contribute to the maintenance and stability of the arch. The tendons of the fibularis longus approximate the medial and lateral borders of the foot. A shallow arch is maintained at the metatarsal heads by the deep transverse ligaments, transverse fibers that tie together the digital slips of the plantar aponeurosis, and to a lesser extent by the transverse head of adductor hallucis.

Muscles acting over the foot

The extrinsic and intrinsic muscle groups act over the foot. The extrinsic group of muscles are further classified into the anterior group, lateral group, posterior group and the superficial group.

The extensors of the foot pass below the extensor retinaculum, and their fibers pass anterior to the ankle joint.

The lateral group of muscles take origin in the lateral compartment of the leg and the tendons pass posterior to the lateral malleolus. It is covered by the fibular retinacula.

The flexors pass posteriorly to the ankle joint. It is divided into the superficial and deep groups. The superficial group inserts into the calcaneum. The deep group condenses into the flexor retinaculum.

The extensor hallucis longus, tibialis anterior, extensor longus and fibularis tertius constitute the anterior group of muscles.

The peroneus longus and peroneus brevis form the lateral group of muscles.

The posterior group of muscles is divided into the superficial and deep compartments. The gastrocnemius and soleus muscles, the calcaneal tendon and plantaris constitute the superficial compartment and flexor hallucis longus, flexor digitorum and popliteus comprise the deep compartment of the posterior group of muscles.

Intrinsic muscles

The intrinsic group of muscles are interspersed within the foot framework. The dorsal group of muscles have extensor action and the plantar group of muscles have flexor action.

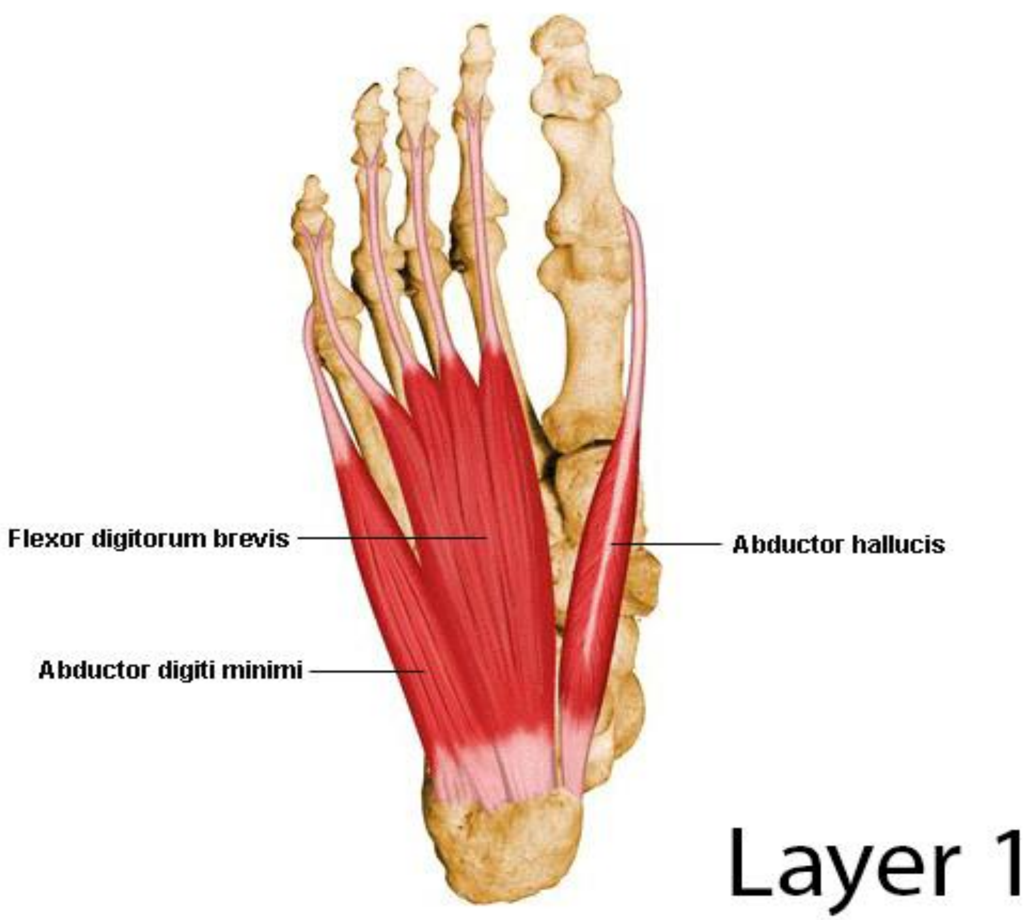
The intrinsic muscles are divided into the medial, intermediate and lateral groups. The medial and lateral groups comprise of the intrinsic muscles of the great and fifth toe respectively.

The intermediate group of muscles comprise of the lumbricals, the interossei, and intrinsic digital flexors.

This grouping is useful in terms of function and also in clinical practice.

Anatomically, these muscles groups are divided into four layers, according the manner in which they are encountered during dissection.

Plantar muscles of the foot: First layer



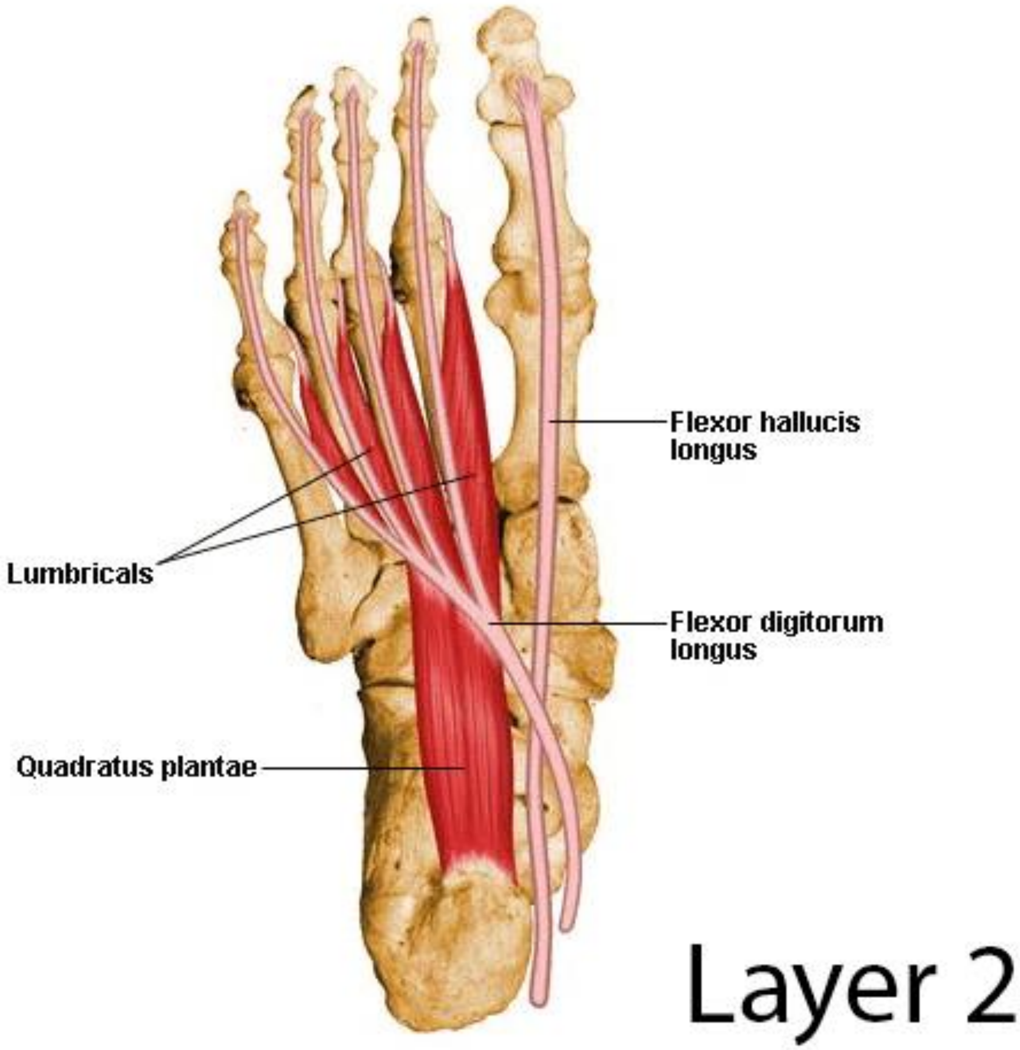
The abductor hallucis, the abductor digiti minimi, and the flexor digitorum brevis constitute the first plantar layer. They take origin at the calcaneal tuberosity and insert into the toes and help in maintaining the concavity of the foot.

The abductor hallucis originates from the flexor retinaculum, and partly from the medial process of the calcaneal tuberosity, and the fibers end in a tendon the attach medially with the tendon of the flexor hallucis brevis, to the medial side of the base of the proximal phalanx of the big toe. The strong fascia comprising these two muscles is used in tissue augmentation following surgical correction of hallux valgus deformity. When it is overactive, it can lead to varus deformity requiring surgical correction.

Flexor digitorum brevis originates from the medial process of the calcaneal tuberosity, from the central part of the plantar aponeurosis, and from the intermuscular septum between it and the adjacent muscles. It divides into four tendons which pass lateral to the four toes, the tendons entering the digital tendinous sheaths. At the bases of the proximal phalanx, it bifurcates into two slips, dividing around the tendon of the corresponding flexor digitorum longus, then reunite and partially decussate, thereby forming a tunnel through which the tendon of the flexor digitorum longus passes to the distal phalanx.

The abductor digiti minimi originates from the calcaneal tuberosity, and fibers of the flexor digitorum brevis. The tendon attaches to the lateral side of the proximal phalanx of the fifth toe after passing through a groove in the base of the fifth metatarsal.

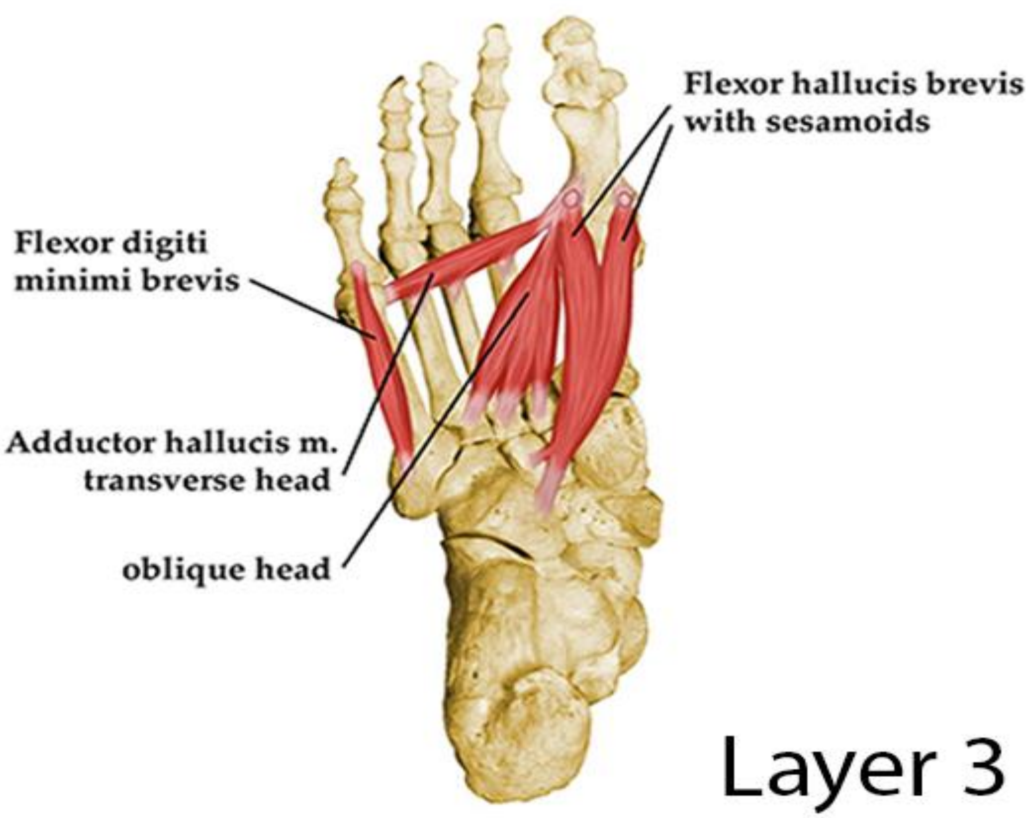
Plantar muscles of the foot: second layer



This is constituted by the flexor accessorius muscle and the four lumbrical muscles. The flexor accessorius (also known as quadratus plantae), originates as two heads, the medial head of which arises from the medial surface of the calcaneus, just below the groove for the tendon of the flexor hallucis longus. The lateral head is more flat and tendinous, and originates from the lateral process of the calcaneal tuberosity. The muscle belly splits into four tendons and inserts into the tendon of the flexor digitorum longus.

The lumbricals are accessory muscles to the flexor digitorum longus, arising as bipennate fibers on either side of the tendons except for the first tendon where it arises only on the medial border. They form the dorsal digital expansions over the proximal phalanges of the four lateral toes.

Plantar muscles of the foot: third layer



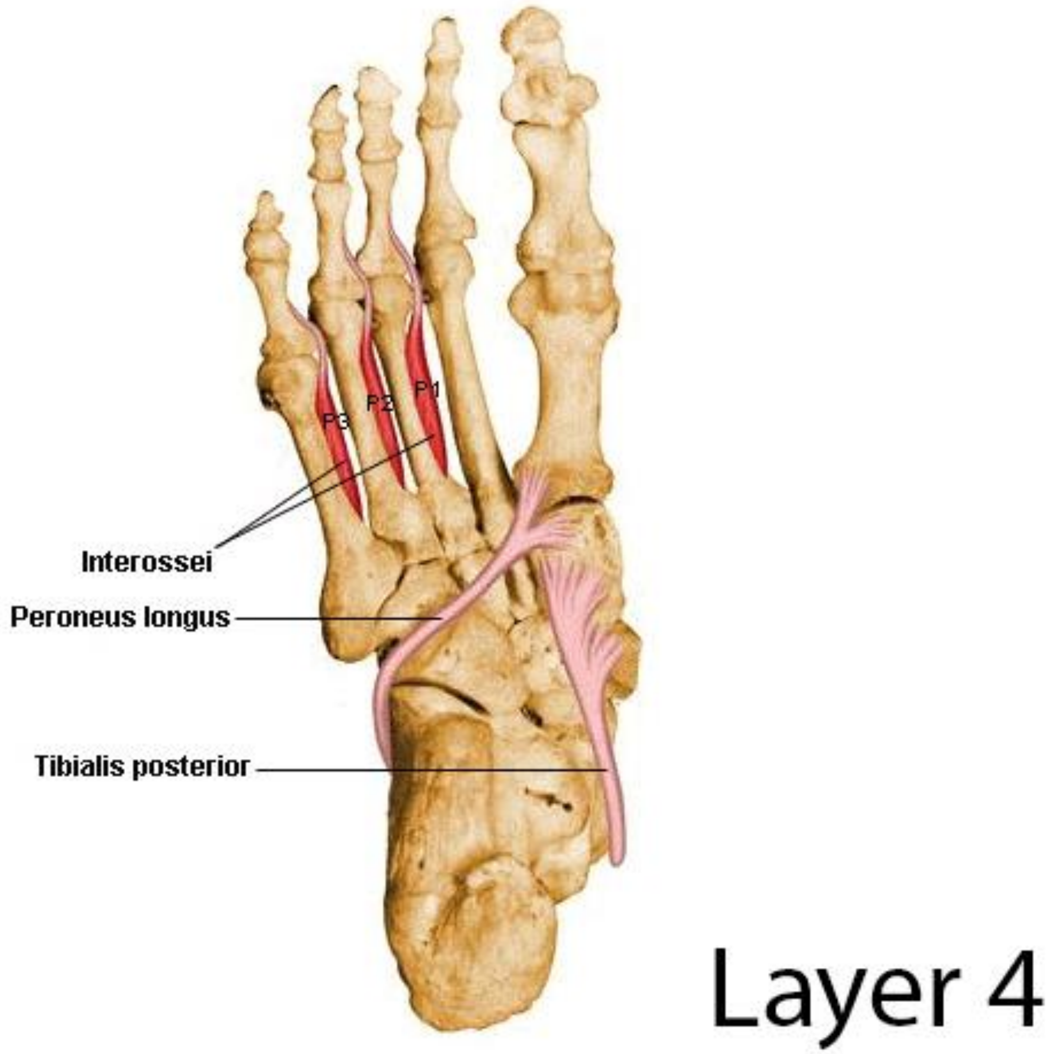
This comprises of the flexor hallucis brevis, the adductor hallucis and the adductor digiti minimi brevis.

The flexor hallucis brevis originates as two tendons, the lateral tendon of which arises from the medial part of the cuboid bone, and the medial tendon from the tibialis posterior tendon. The belly is also divided into medial and lateral parts, with the twin tendons attaching to either sides of the proximal phalanx of the great toe.

Adductor hallucis arises from the bases of the second, third and fourth metatarsals, and blends with the fibers of the flexor hallucis brevis, inserting into the base of the proximal phalanx of the great toe.

Flexor digiti minimi brevis arises from the medial part of the plantar surface of the fifth metatarsal and inserts distally into the base of the proximal phalanx of the fifth toe.

Plantar muscles of the foot: fourth layer



The plantar and dorsal interossei and the tendons of tibialis posterior and peroneus longus constitute the fourth layer.

The dorsal interossei arise in between the metatarsals and insert into the bases of the proximal phalanges and the dorsal digital expansions. There are three plantar interossei, arising from below the third, fourth and fifth metatarsals and inserting into the medial aspects of the bases of the proximal phalanges of the corresponding toes.

Surgical principles of amputations

Correlation between nutrition of patient and level of amputation: Studies done by Dickhaut et al. and Kay et al showed that patients with normal nutritional parameters had a normal post-operative course with good stump healing whereas in malnourished patients, atleast fifty percent had complications such as non-healing ulcers (22). Hence, the rate of wound healing would be lower with higher post-operative complications if the serum albumin level was less than 3.5gm/dl or total leucocyte count was less than 1500 cells/ml(23). Waters et al compared the energy costs of walking required for patients with major or minor amputations. On comparing with controls without amputations, it was concluded that minor amputations would result in better performance and lower energy expenditure. It is confirmed that the lowest level of amputation must be performed, if preservation of function is the chief concern(24).

Technical aspects: The ideal stump length is between 12cm to 18cm. As it may vary according to height, the rule of thumb is to give a 2.5cm bone length for every 30cm of height. An acceptable length is atleast 15cm distal to the medial tibial articular surface.

Scar tissue and its location used to be an initial problem post-operatively. However, with the advent of total contact prosthesis sockets, scar location is not of much concern. However, is the scar is adherent to underlying tissues, then it can undergo friction and eventually breakdown after repeated prosthetic use. Redundant soft tissues or ‘dog ears’ also create problems in prosthetic fitting.

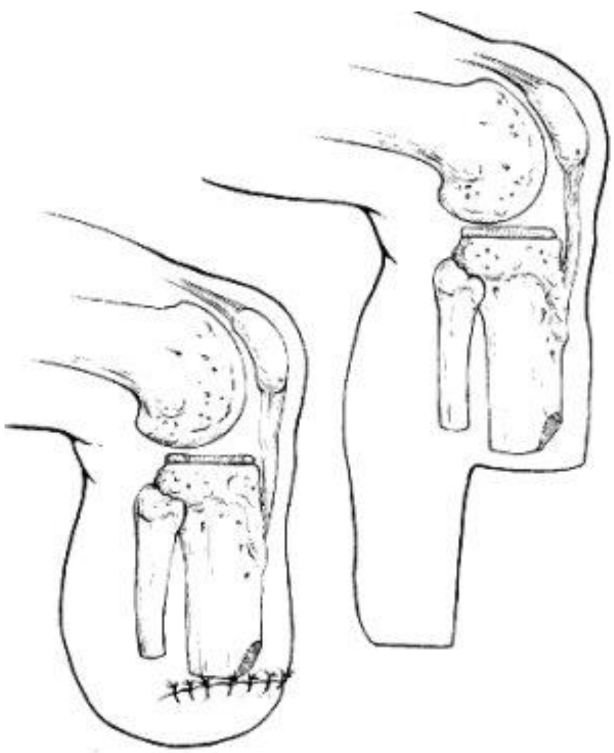
Muscles, after resection from their origin are usually sutured through myodesis, i.e. suturing muscles or tendons to bone, or myoplasty, i.e. suturing the muscle to the periosteum or fascia of the opposite musculature. The preferred method, if possible, is myodesis, as it maximizes wound strength, improves limb function, and minimizes the risk of wound contractures or muscle atrophy. However, its use in limb ischemia is contraindicated due to the high risk of wound breakdown(25).

Staged amputations (usually two-staged), can be done in cases of severe infection, and/or trauma. In the first stage, a guillotine amputation is done as a means of immediate source control for the infection. This is usually followed by closure, higher amputation, revision of the wound or plastic repair(25) (26).

Techniques for below knee amputations

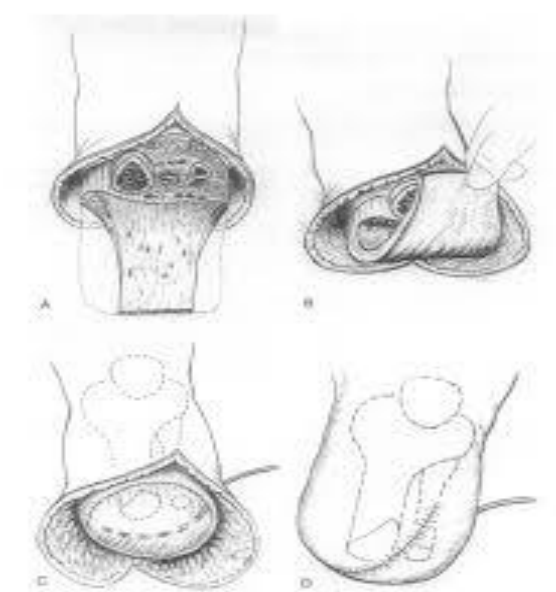
Various techniques have been described for a transtibial amputation, keeping in mind that the residual stump must be a strong and functional one. At the same time, healing of the stump must be taken into consideration. These two factors can be sometimes in opposition to each other. The higher the level of amputation, the better the chances of healing, but more the morbidity and mortality associated with higher amputations along with difficulties in rehabilitation(27). It has to be ensured that the vascularity of the distal stump and flap is not compromised and popliteal pulses are present. The following techniques have been described in literature for transtibial amputations.

(a) **Burgess posterior flap technique -** The most common technique used for transtibial amputations. Anteriorly, a short skin flap is raised about 12-15cm from the tibial tuberosity and the posterior flap is a much longer one, involving the fibres of the gastrocnemius and soleus muscles.



The tibia and fibula are divided about an inch from the skin incision and the edges are smoothened. The muscles of the posterior flap are then trimmed and approximated anteriorly to the anterior tibial muscles, the anterior fascia and reflected periosteum. The skin edges are approximated in a similar fashion, with or without drain placement. The advantages of this technique were that, the myoplasty of gastrocnemius and soleus muscles helps in venous return and also enforces knee flexion. An added advantage also that the final shape of the stump fits most of the modern prostheses and provides a good cosmetic result. The disadvantage being that there is a potential for ischemia of the flap. (27)

(b) **Skew technique**: This technique is based on creation of equal anteromedial and posterolateral fasciocutaneous flaps. This helps in preserving the knee joint in patients who may have just marginally viable skin below the knee joint and otherwise may warrant an above knee amputation.

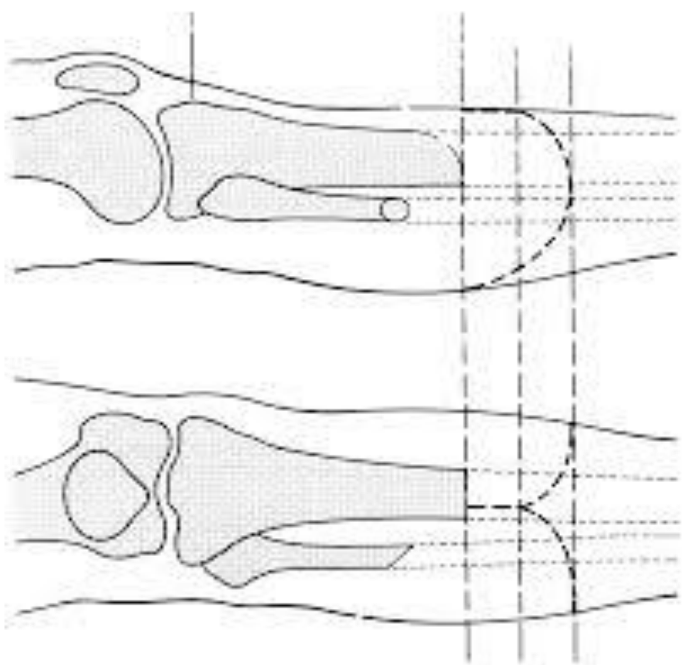


This is based on the vascular assessment that there is a significant medial to lateral blood flow gradient, allowing a medial based flap, and has been shown to successfully salvage the limb, allowing for early prosthetic fitting and mobilization.(28)

(c) **Sagittal –** This technique involves creation of medial and lateral myocutaneous flaps which are of equal caliber.

(d) Medial – This technique constructs a long medial and a short lateral flap.(28)

(e) **Medial fish-mouth –** This includes equal anterior and posterior flaps.



Postoperative complications

Post-operative morbidity and mortality rates are high in Diabetics due to the presence of other comorbidities such as renal or cardiovascular disorders. Complications could be pertaining to wound healing or other comorbidities such as peri-operative cardiac events, acute kidney injury, urinary tract infections or respiratory complications. Below knee amputations have been associated with more complications than above knee amputations. (29) Below knee amputations are associated with a 5-10% post-operative mortality as compared to above knee amputations where mortality is 10-17%. Overall survival is reported at 69-78% at 1 year and 33% at 5 years. (30). Perioperative adverse events include cardiac and pulmonary complications, pressure sores, sepsis, bleeding, re-operation and wound infection. Urinary retention, although considered a minor complication, can add to the morbidity of the patient, and urinary catheterization must be considered in patients undergoing major lower limb amputations, especially above knee amputations. Irreversible complications include cerebrovascular accidents. Shortcomings in the operative technique would lead to complications such as stump necrosis or post-operative hemorrhage.

As mentioned earlier, a higher number of healing problems were observed with below knee stumps as compared to above knee amputations. This is due to the fact that there is impaired microscopic vascularization at the level of the amputation and therefore, choosing the correct level of amputation, especially in below knee amputations, is imperative in such situations. (31)

It has been observed that necrosis of the stump after a below knee amputation can be managed conservatively in majority of cases. However, in cases of stump infection associated with impaired vascularity, a higher level of amputation may be warranted. The below knee to above knee conversion rate in literature has been about 14.3%. (29)
Ulcers are a common complication. They occur at the site of bony prominences of the stump site where adequate soft tissue cover has not been given, or bone edges have not been rasped or smoothened out. This usually happens on the anterior aspect of the tibia after below knee amputations and lateral side of femur for above-knee amputations. (32) Skin conditions in the residual limb play an important role in the development of ulcers. Skin conditions such as folliculitis, epidermoid cysts, contact dermatitis or eczema can lead on to ulcer formation at the stump site as emphasized by Levy et al in 1956. Hence stump hygiene in amputees is imperative and cannot be overlooked. While walking and weight-bearing, the skin at the stump site is exposed to repeated shearing forces. Any breach in the skin along with concomitant skin conditions can predispose to ulcers. This added to other factors such as poor patient nutrition, ill-fitting prosthesis, poor vascularity at the stump site, poor hygiene and bony prominences can all contribute to stump ulceration. (33)

A study done by Berridge et al showed that in amputees who had pre-operative sepsis, poor nutritional status, advanced age or development of wound hematomas post operatively developed stump site infections. There was no significant difference in the wound sepsis rate of diabetic patients. (34)

Phantom limb pain has been described in war veterans undergoing major amputations. It has been described as a burning, aching, electric-type pain in the amputated limb. It was first described by a French military surgeon Ambroise Pare. It consists of three distinct elements – pain sensations that are being referred to the amputated limb, sensations other than pain being referred to the amputated limb, and pain localized at the stump site. A lot of theories have been postulated for mechanisms of phantom limb pain which are debatable. Following amputation, there may be the formation of a neuroma, which may show spontaneous activity on mechanical or chemical stimulation due to upregulation of sodium channels. Neuromas are formed at the level of the nerve transection and become painful if they are located superficially in areas more prone to increased pressures. Hence, various methods of isolating and burying nerve bundles during amputation are being practiced, keeping in mind that strong tension and crushing of the nerve bundles should be avoided.

Other factors suggested are increase in c-fiber activity, abnormal activity of the dorsal root ganglion, distorted sympathetic acitivity and over-excitability of spinal neurons. The incidence of phantom limb pain has been found to be 49-88% in recent literature. (35)

Residual lower limb characteristics

Following amputation, rehabilitation mainly aims to restore functional independence of the individual through ambulation using prosthesis. To fit a conventional prosthetic limb using a socket, requires changes in the soft tissues residual limb including their shape, volume, sensitivity, scarring from surgical wounds and tissue composition. These factors depend upon tissue hydration, temperature and activity and also the amount of muscle atrophy, reduction in postoperative edema and tissue remodeling that eventually determines socket-skeleton load transfer. This transfer must be comfortable and most prosthesis are modified accordingly such that it is physiologically sound and the required biomechanical targets are achieved. This otherwise can lead to ill-fitting sockets, which in-turn can lead to injury of the stump site, and secondary musculoskeletal changes such as osteoarthritis, osteoporosis and lower back ache. (36) In below knee amputation, a soft tissue pad is created by the gastrocnemius and soleus muscles over the resected surfaces of the tibia and fibula which is anchored to the periosteum over the anterior tibial surface. This is then covered by a posterior skin flap or a skewed flap which seals the muscles. During ambulation using prosthesis, this soft tissue cover is subject to shear stress along the muscle fibers as well as transverse stress. It is also subject to strain around bony prominences such as the anterior surface of the tibia. Eventually, the tibial plateau, anterior surface of the tibial shaft covered by skin, and the patellar tendon become the primary load-bearing surfaces. Hence, it is imperative that the residual limb have certain characteristics for effective skeleton-socket load transfer. Anatomical factors include length of the residual limb, range of motion of the proximal joint, presence of any deformities or contractures, condition of the skin at the stump site, volume (edematous changes), location of the surgical scar and its condition.

This is also determined by individual patient's geographical location, and the goals and activities of the individuals.

The length of the residual limb can be varied depending on the level of amputation. It can be long, with up to 80 percent of limb length preserved, medium, with 50 percent of preserved limb, or short, with less than 30 percent of the residual limb. The residual stump, therefore, must have the following characteristics (37):

- Ideal limb length
- Bony prominences well-covered by muscle and skin
- No edema, open wounds or infection
- No neuromas
- No contracture or deformity in the joint proximal to the stump
- Full range of movements in the proximal joint.

Transtibial prosthesis

The following principles must be remembered while prescribing prosthesis:

- The mobility needs of the patient must be met.
- The prosthesis should provide maximal independence and good functional outcome
- The prosthesis must be cosmetically acceptable
- It must be cost-effective

- It should not cause any pain or discomfort during ambulation. An ill-fitting prosthesis may injure the stump site, cause grievance to the patient, and eventually lead to disuse of the prosthesis.

Other prosthesis characteristics include the quality of the suspension system, which if poor, can lead to pistoning of the residual limbs. Equally important are the contour and design of the socket, the type of socket material, the interface material that is used which is interposed between the hard socket and the soft residual limb, the prosthetic pylon and its ability to absorb or dissipate forces, and the integrity of the footpiece. (38)

A transtibial prosthesis thus has the following components:

- 1) Sockets with inner surface lined by silicon which reduces the area of contact of the skin of the residual limb with the socket and reduces chances of ulceration. The patellar tendon weight-bearing socket (PTB) is the most commonly used design. Other modifications of this include the Patellar tendon bearing –Supracondylar (PTB-SC) and Patellar tendon bearing – Supracondylar, suprapatellar (PTB-SCSP) sockets which are more useful in residual limbs with shorter length. Other alternatives such as the Total surface bearing (TSB) and hydrostatic sockets are increasingly being accepted. (39)
- 2) A suspension system which includes straps, most commonly cuff straps resting on the supracondylar region, prosthetic sleeves, suction and gel liners with locking mechanisms.(40) There are various materials for suspending the sleeves of a socket which can be pulled up to the thighs after wearing the prosthesis.

There are mechanisms to create airtight vacuum at the bottom of the prosthesis in various prosthetic designs. (41)

- 3) An endoskeletal pylon which helps in shock absorption and reduction of energy expenditure. It is available in various materials and can be fabricated and altered according to the requirement of the prosthesis.

- 4) The foot-piece of the prosthesis completes the prosthesis. It may be a basic or a dynamic foot-piece. Solid ankle cushion heel (SACH) foot is the most commonly and widely accepted basic prosthetic foot. Articulated prosthetic feet may come as single or multi-axial joints. Dynamic foot-pieces help in pushing the leg up during the push-off phase of the gait cycle and hence reduces the impact of the normal foot with the ground. (41)

Jaipur foot is a popular option for prosthesis which is commonly used during rehabilitation. It was designed by Dr Ram Chander Sharma. During its inunciation, polyurethane was the material used for making it. The advantages of this particular prosthesis were that it was inexpensive, water-resistant, easy to manufacture and designed to fit well. We now have premier organisations providing low cost prosthesis to amputees across the world. (42)

Biomechanics of the foot in Diabetes Mellitus

Diabetes Mellitus causes distal symmetric polyneuropathy which causes sensory loss as well as loss of protective reflexes in the foot. During ambulation, this causes several biomechanical factors to come into play and predispose to injury and ulcer formation. Therefore knowledge of biomechanics plays an important role in neuropathic injury. (43) Majority of the injuries occurring on the feet of diabetic patients occurs in the forefoot. They are equally distributed on the dorsal and plantar surfaces. Of those on the plantar surfaces, the majority occur in areas of high pressure, namely the metatarsals. Hence in-shoe measurement techniques can help in prescribing appropriate therapeutic footwear. Biomechanical techniques can also help in evaluating other consequences of diabetic foot, such as foot deformity, bony abnormalities, callus formation or restricted joint mobility.

Earlier estimation of pressure was done by video analysis of movements. However, it is subjective and does not allow evaluation of the forces between the foot and the ground or various forces acting between the foot and the various type of footwear. Kinetics, or the study of forces acting on the foot during movement, is the area of mechanics which investigates this. The external forces act on the foot from the ground or the footwear, and internal forces act between the articulating surfaces of joints.

It was stated aptly by the late Dr. Paul W. Brand in his paper – pressure is the critical quantity that measures the harm done by force (44). In effect, it is the determined by the amount of force acting over the area of the foot. Hence, forces acting over a very small area of the foot through bony prominences can be much more devastating as compared to the same forces acting over a larger area. Hence, the importance of plantar pressure measurement in diabetic-foot injury.

In the diabetic foot, several biomechanical factors come into play which result in some maladaptive structural and functional changes in the foot. The most important causative factor in this regard being peripheral neuropathy. Any form of neuropathy can lead to subtle changes within the foot joint, affecting its articulation, elasticity of tendons, ligaments and soft tissues, and thereby resulting in faulty biomechanics of the foot. Joint immobility can lead to subluxations within the foot and associated with loss of elasticity and tensile strength of the joints. Charcot's neuro-arthropathy is such an example, where contracture of the Achilles, and loss of spatial orientation of the bones of the foot result in a downward cascade, thereby culminating into ulcer formation. (45)

A typical gait cycle comprises of a stance and a swing phase. The swing phase is the period where there is no weight-bearing and the foot clears off the ground. During the stance phase, the foot lands on the heel first, with the weight bearing proceeding up to toes as the body propels forwards and the foot moves into the subsequent swing phase. At a certain short while during the stance phase, the foot bears the entirety of the body weight as it forms a rigid lever.

There has been no definite threshold for plantar pressures which can predispose to ulceration. Several reasons have been cited for this. Firstly, the platform on which pressures were assessed was not extrapolated to other platforms. Also, different areas of the foot have different tissue threshold for breakdown. This depends on the vascularity in that region, the amount of glycosylation, tissue perfusion and scarring. Also, shear forces are not measured by any of the currently available platforms. The time-integral product of pressure, which is usually never calculated, may be more relevant than just peak pressures. Lastly, barefoot measurements that are checked across a platform may not be truly representative of the actual pressures experienced by the foot, which may be determined by the footwear and the level of patient activity. Hence, plantar pressures reflecting that of a normal population cannot be compared to that with insensitive feet. Neuropathic patients, with low pressures are also prone to ulcer formation. Hence, there can be no threshold value that can be defined.

Plantar pressures

Pressure (also called stress) is defined as the amount of force acting per unit area. During ambulation, plantar pressure assessment can be done using discrete sensors or a matrix of multiple sensors in direct contact with the sole of the foot and the supporting surface. The sensors have a fixed unit area. According to the System International (SI), the standard unit of force is Newton and the standard unit for pressure is in Pascal. Hence, Pascal is defined as the force in Newton, acting per meter square of an area of the sensor or sensors which were evoked at the time of contact of the foot with the supporting surface. Pressure can also be expressed as pounds per square inch, Newton per centimeter square, or kilograms per square inch, but kilopascals or megapascals are the preferred standard units of pressure measurement.

Need for plantar pressure measurement

Development of ulcers in a Diabetic foot is a multifactorial process, that includes development of neuropathy, minor foot trauma and foot deformities. Elevated plantar pressures, and development of ulceration at that specific site, have been correlated. This has been done both retrospectively and prospectively. (46) (47) Studies have shown that metatarsals are at a higher risk for development of ulcers due to elevated plantar pressures as compared to the rest of the foot. This can be explained by the fact that during gait, maximum loading of the body weight occurs at this point, just before the swing phase. It can also be attributed to the complex anatomy of this region. As compared to the hallux and heel, which are biomechanically the other prominent points for elevated plantar pressures and ulcer development, the anatomy at the metatarsal heads is more heterogenous and complex. The hallux and heel have thicker plantar soft tissue and are prone to ulcer formation due to shear stress or ischemia. (46)

The pressure fields at various points provide the site of interaction between the foot and the external environment during ambulation. Measurement of foot pressures will help in early identification of sites of injury and its prevention, and general well-being of the patient. An early intervention in the form of footwear modification, or prosthesis alignment can help in preventing ulcer formation and subsequent injuries and contralateral amputation in the long term. The earliest application of plantar pressure measurement was, in fact, for evaluation of footwear as showed by Lavery et al. (48) Queen et al showed that rocker bottom soles effectively reduced pressures at the metatarsal heads, and also that there was a difference in the loading patterns between genders. (49)

Various methods of plantar pressure measurement

Foot pressure measurement systems have been developed over the last two decades and have been revolutionized due to intricate computerized systems. These systems have major clinical and research implications in terms of early intervention in the form of footwear modification, prosthetic or orthotic alignment or early surgical intervention. The pressure measurements may be obtained in the form of out-of-shoe, or in-shoe methods.

The earliest application of plantar pressure measurement was demonstrated by Beely et al (1882).(50) Here, patients were made to ambulate over sack-cloth filled with plaster of paris which would produce foot imprints. The deepest impression would signify areas with the highest loading pressure. This was a primitive and crude method for measuring plantar pressures and had its own flaws. It only took into account the impression created rather than measurement of actual pressures. It was more qualitative and had poor intra- and inter-observer reliability.

There are several measurement systems that are still being developed. Most of current research is based on developing in-shoe systems which can measure vertical ground forces and shear forces at the same time. Several piezoelectric transducers have been developed which can do so and provide valuable information on pressure development during in-shoe ambulation. These are being employed for the management of diabetic foot complications and variety of other foot conditions.

In 1930, Morton (50) introduced the kinetograph, which was a deformable rubber pad placed over an inked sheet underneath and the subject would be made to ambulate over the pad. It was the earliest documented attempts to measure foot pressures instead of forces. Elftman (50) developed the barograph, which allowed for measurement of dynamic pressure changes as the patient ambulated. It consisted of a rubber mat with a smooth surface on top where the patient ambulated, and multiple, fine pyramidal projections below, whose area increased according to the area of pressure increase under the foot. A video camera from below recorded the pattern of deformation under the mat as the patient walked.

Harris and Beath, in 1947, used a mat, now named after them, to study foot problems and foot related pressure changes in a large number of Canadian soldiers. (51) It used a multilayered, inked rubber mat on which patient would ambulate, in contact with a sheet of paper below. As the patient would ambulate, the ink from the rubber sheet would escape onto the sheet thereby creating an imprint of pressure mapping. The areas with more dense ink-staining would represent higher plantar pressures.

Barrett and Mooney (52) utilized the principle of the Harris Beath mat, and found very high pressures under the feet of diabetic patients. A main disadvantage of the device was that it could not be calibrated to various degrees of foot pressure. As a result, the mat would saturate at higher levels of foot pressure. Furthermore, it was not a standardized method as the ink placed onto the mat was not standardized. The mat was later calibrated using a contact area of known size and weight, thereby producing semi-quantitative and qualitative data. The major drawback of this device being that it only measures static plantar pressures and does not aid in dynamic plantar pressure measurement.

MATERIALS AND METHODS

This study aims at evaluating the hypothesis that prosthesis is more effective in offloading the precious limb following a transtibial amputation as compared to orthotic devices like crutches or walkers.

This trial was approved by the Institutional Review Board and Ethics Committee of Christian Medical College, Vellore. The cases were recruited from three areas:

- The General surgical wards P1, P2, P3
- The Diabetic foot clinic – Medical Endocrinology
- The Physical Medicine Rehabilitation center – PMR

ELIGIBILITY CRITERIA

Inclusion criteria

1. All diabetic patients who have undergone a below knee amputation and have been rehabilitated with axillary crutches and come for the pre-prosthetic training were recruited
2. Those patients who give a written consent for the study will be included.

Exclusion criteria

1. Any patient who has undergone an amputation for a non-diabetic cause; for example, a traumatic cause.

2. Those patients who have undergone a concomitant procedure for peripheral arterial disease.
3. Those patients with a known spinal or musculoskeletal deformity.

Diabetic patients who had undergone elective or emergency below knee amputation due to a diabetic ulcer were explained about the study and consented. Those patients who underwent amputations for traumatic injuries, gangrene due to peripheral arterial occlusive disease, or malignancies (causes not due to a diabetic ulcer) were excluded from the study.

The patient underwent the following sets of clinical evaluation and assessment:

- Sensory assessment of the precious (contralateral) limb involved
- Plantar pressure assessment of the precious limb
- Biochemical assessment of the diabetic status of the patient

Sensory assessment

The Semmes-Weinstein monofilament was used for this purpose which uses nylon monofilaments mounted on a Lucite rod and provides a standard stimulus for light touch on the plantar aspect **(Fig. 1)**. The 5.07 monofilament was used which provides a standard stimulus of 10g. Failure to sense the 10g monofilament is used as the determining factor for using protective footwear and accommodative orthotics. The monofilament tests the single point perception test. It is placed on the skin till the filament bends. The monofilaments are standardized and tested to be reliable at 95 percent confidence interval. The sensory assessment was done at five plantar points, the hallux, the medial forefoot, the lateral forefoot, the midfoot and the heel.

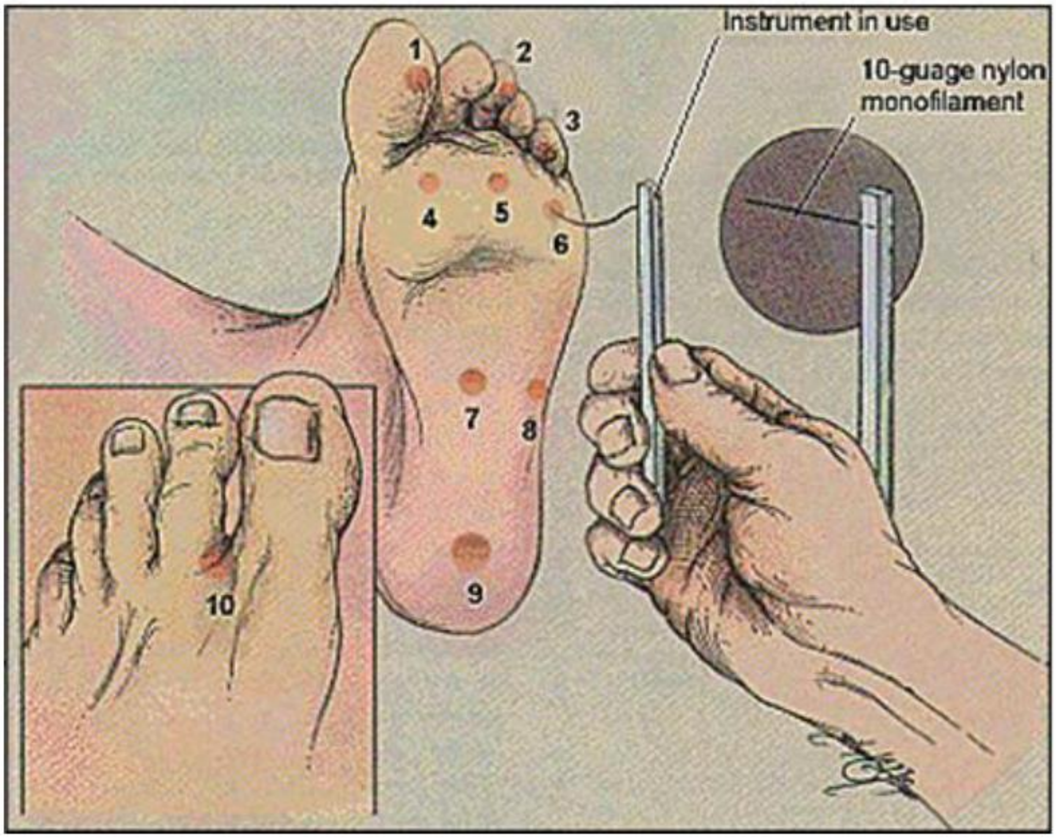


Fig. 1 Sensory assessment using Semmes-Weinstein 10g monofilament

Plantar pressure measurement

The tool used to measure plantar pressures was an in-house device in the form of an insole with micro-sensors embedded in it. The micro-sensors were placed at five specific points, the hallux, the medial forefoot, the lateral forefoot, the mid-foot and the heel.

The insole was placed inside the footwear of the precious limb and the patients were asked to ambulate for a distance of 10 meters, once with the prosthesis and once without it, using crutches or walkers. (**Fig. 2**)

Fig. 2 Insole with pressure probes embedded at five points within cellophane sheets

The pressures are transmitted through wires connecting the insole to a computer which will display graphical data depicting plantar pressures at each sensor with respect to time. This data was then used for both quantitative and qualitative analysis.

Fig. 3 Insole with CMC Daq device

Pressures obtained at a certain point which were high warranted an intervention in the form of footwear modification, or prosthetic fittings and adjustments. The main aim would be to detect early increased pressure changes at that point and prevent ulcer formation which can progress to severe Diabetic foot infections and subsequent amputation.

Fig. 4 Insole with probes adjusted in the patient footwear

Fig. 5 Device connected to computer for recording

The software used for graphical representation is CMCdaq which was developed by the Department of bioengineering.

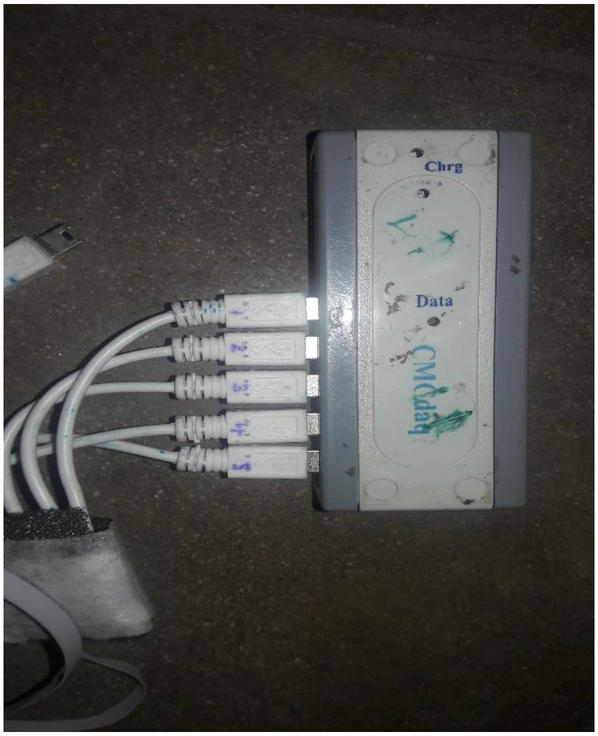


Fig. 6 CMC Daq device

We will attempt to extrapolate the results of our study at a later date along with data representing vascularity and oxygenation in the precious limb, and further intervention required to preserve that limb. This will be part of a later study.

Biochemical assessment

This included fasting and post prandial sugars and HBA1c measurements

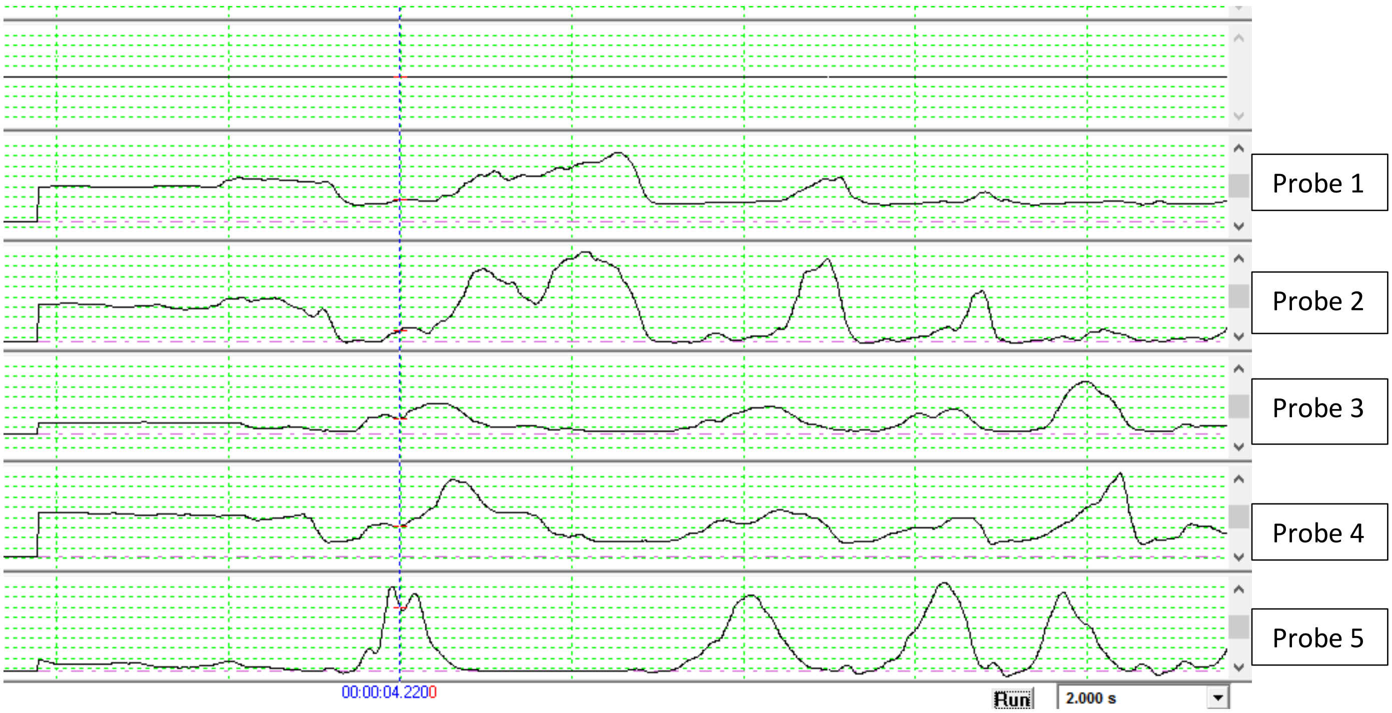


Fig. 7 Normal gait pattern using prosthesis in a Diabetic amputee

Here, Probe 1 refers to the hallux, Probe 2 first metatarsal head, Probe 3 fifth metatarsal head, Probe 4 lateral midfoot, and Probe 5 is the heel. X-axis refers to the time Y-axis refers to the amplitude of pressure The graph shows a normal pattern of gait as expected in a gait cycle, with heel strike commencing the gait cycle and progressing eventually towards the hallux before the lift off phase prior to the next cycle. The graph demonstrates variation in gait pattern, amplitude of pressures at each point, and also the duration for which these pressures are sustained. Hence a qualitative analysis of the graph can help in early detection of pressure changes.

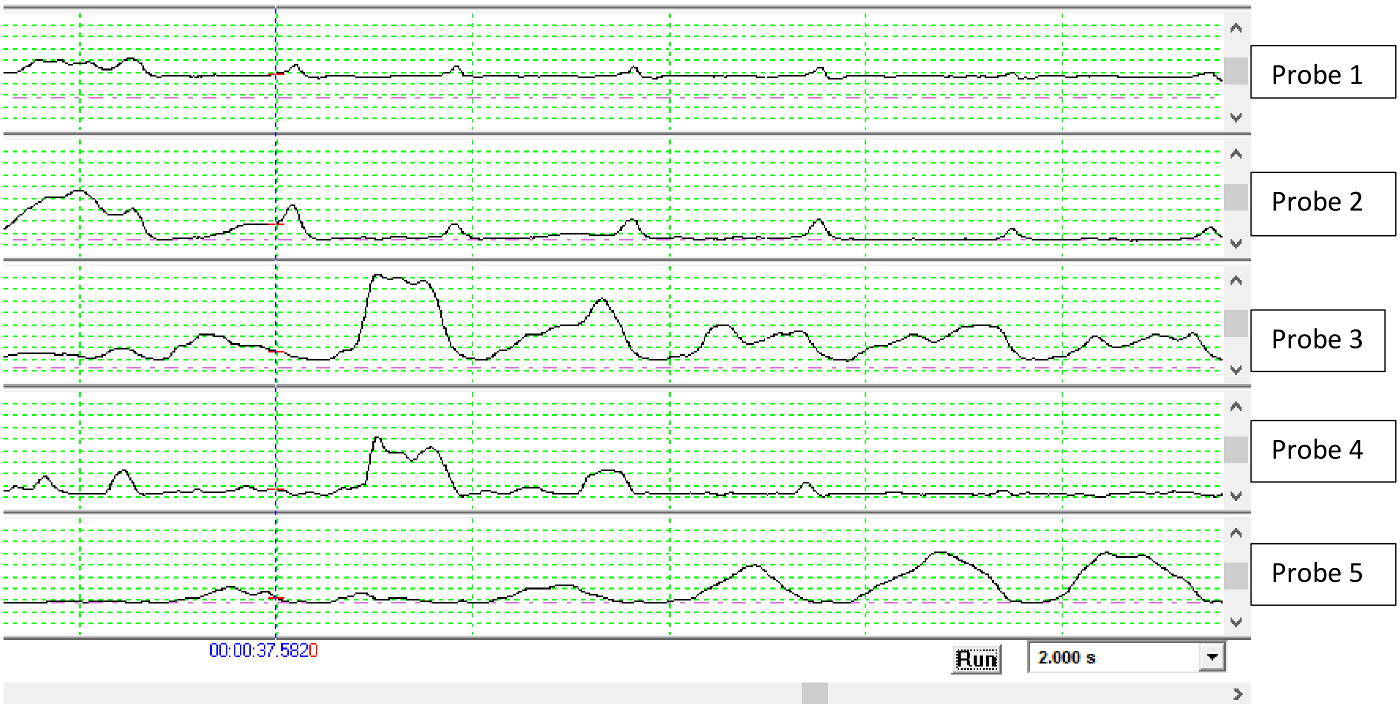


Fig. 8 Abnormal gait pattern seen in the same patient without prosthesis while using walker

Here, the gait pattern is seen to be commencing from the first metatarsal head, contrary to normal gait, with high amplitude sustained pressures over the fifth metatarsal head and lateral midfoot. It is an early indicator of undue pressures due to abnormal gait and abnormal landing of the foot with uneven pressure distribution while using crutches or walkers.

Fig. 9 Ambulation with prosthesis

Fig. 10 Ambulation with walker, without prosthesis

STATISTICAL METHODS

Sample Size

The reference for sample size calculation was on the basis of a pilot study conducted over a duration of three weeks in the Amputee clinic and Diabetic foot clinic.

The mean of peak forces at different plantar pressure points with and without prosthesis was found to be 5 Newtons and 9.33 Newtons respectively, the difference being about 4.33 Newtons.

The difference of peak plantar pressures during gait with and without a prosthetic device was found to be 19kPascal.

The formula used for the sample size calculation was:

Formula

$$N_{pairs} = \frac{\left(z_{1-\alpha/2} + z_{1-\beta}\right)^2}{\Delta^2} + \frac{z^2_{1-\alpha/2}}{2}$$

$$\Delta = \frac{(\mu_2 - \mu_1)}{\sigma} \qquad \sigma = \frac{\sigma_1 + \sigma_2}{2}$$

Where,

μ_1 : Pre-test mean

μ_2 : Post-test mean

σ_1 : Standard deviation in the pre-test

σ_2 : Standard deviation in the post-test

Δ : Effect size

α : Significance level

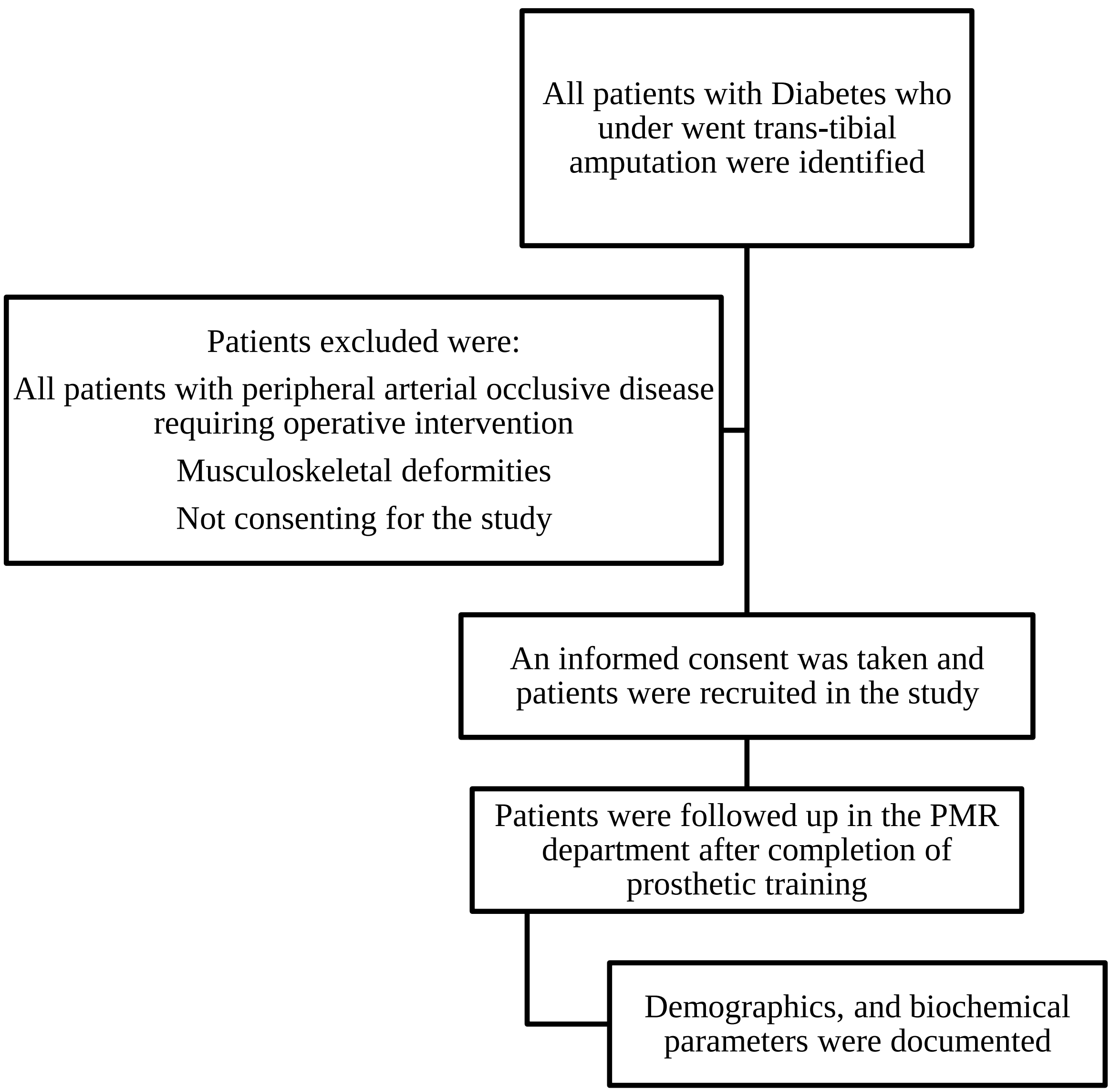
$1-\beta$: Power

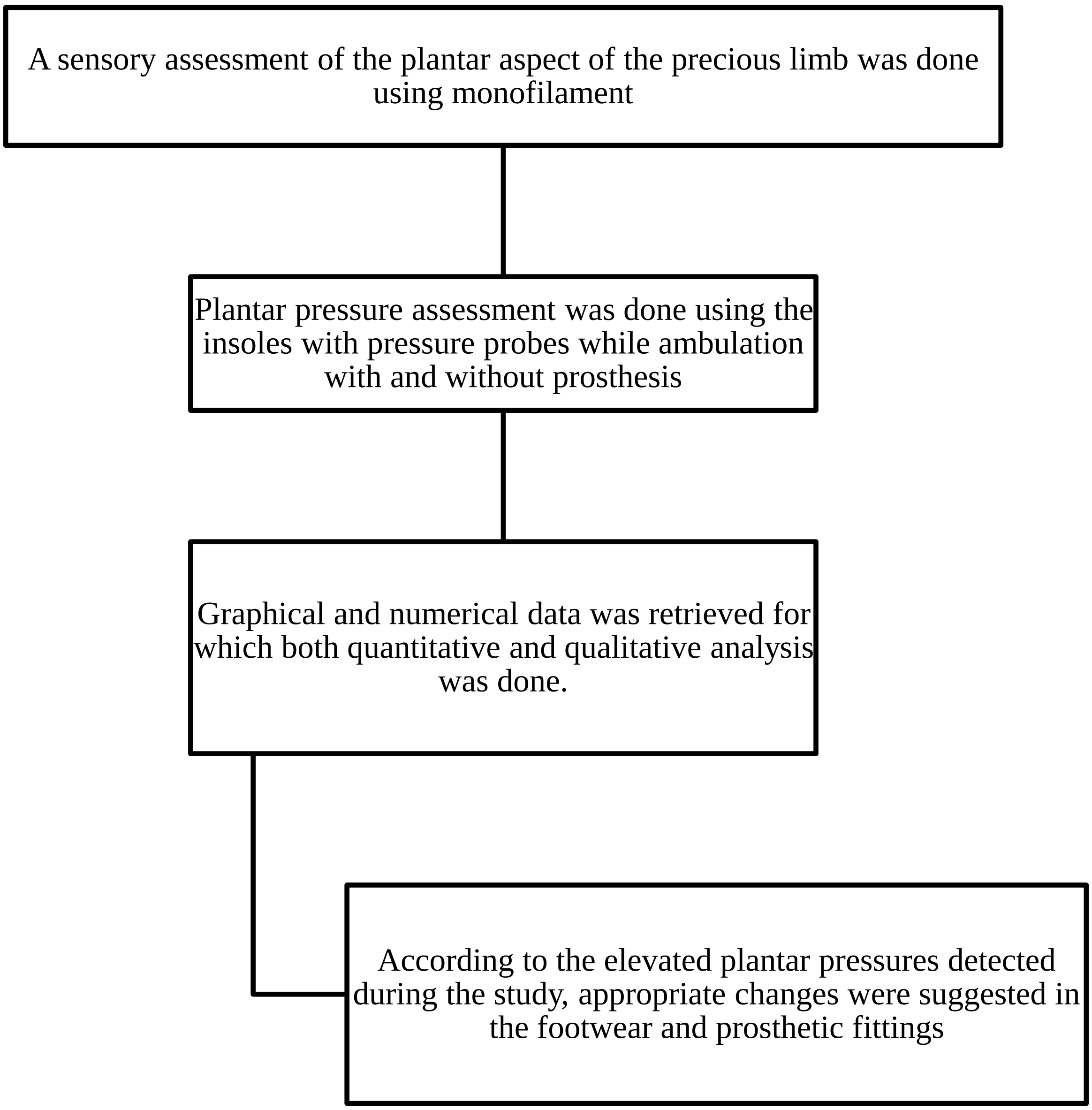
The calculated sample size was 51 patients.

Methods of statistical analysis

All baseline variables were expressed in terms of mean +/- S.D if they were continuous variables. All categorical variables were reported using frequencies and percentages. The distribution of plantar pressures without and with prosthesis measured were checked by plotting the histogram and QQ plot. If the distributional assumption satisfies normality, then the baseline and post intervention measurements will be expressed as mean and standard deviations. If there was any deviation from normality on Shapiro Wilk's test then median with inter quartile range would be reported. The comparison of plantar pressures without and with prosthesis would be done using the Paired T-test if the assumption of normality holds good. If not, Wilcoxon signed-rank test will be done to compare plantar pressures without and with prosthesis. The effect of intervention would also be obtained using ANCOVA after adjusting for covariates, if those covariates may be thought of as confounders.

STUDY ALGORITHM





Data entry was done using Epidata version 3.1 and analyzed using SPSS version 25.

RESULTS

Recruitment

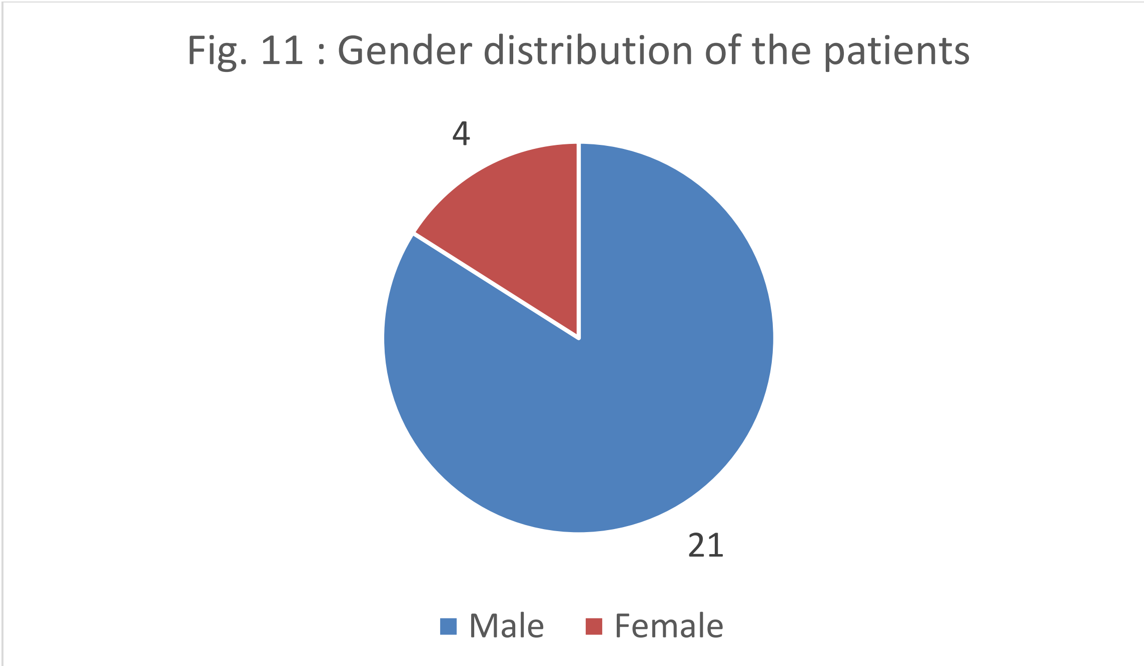
A total of 25 patients were analyzed between the period of January 2017 to July 2018.

The total sample size of 51 patients was not achieved due to the following reasons:

- 11 patients – lost to follow-up
- 3 patients expired after recruitment (due to causes unrelated to the study)
- 7 patients – financial constraints
- 5 patients – local causes – edema unresolved, non-healing stump ulcer

Demographic data

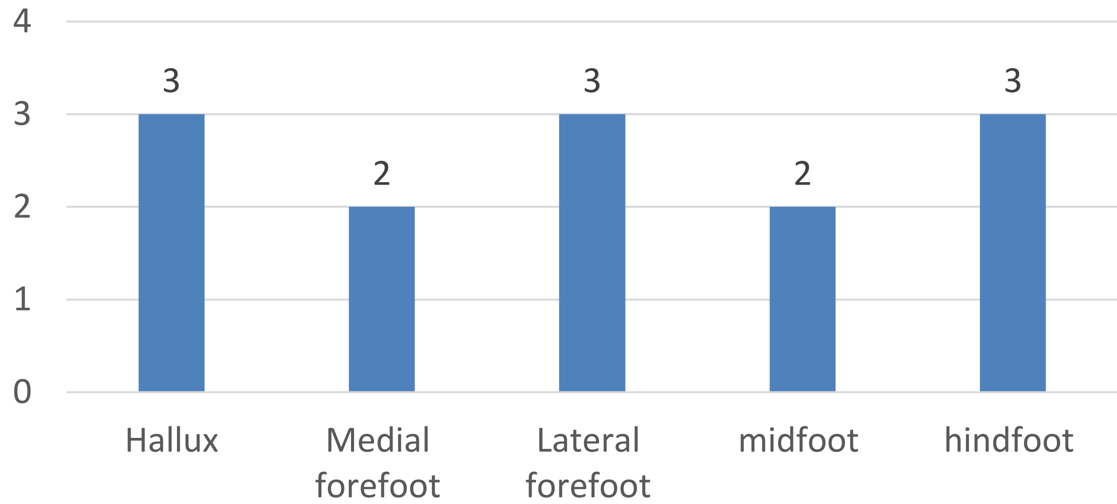
A total of 25 patients were recruited for this study. Amongst these, 21 were male patients and 4 were female patients **(Fig. 11)**. The mean age distribution of the patients in the study was 58 years. The mean Body Mass Index (BMI) of the patients recruited in the study was 24.6 kg/cm^2. The mean glycosylated hemoglobin (HbA1c) values in these patients was 8.8%.



Sensory assessment

The site-specific sensory assessment using a 10g Semmes-Weinstein monofilament showed the following distribution of absent fine pressure sensations at specific sites on the plantar region. **(Fig. 12)**

Fig. 12 : No. of patients with absent fine pressure sensation at different points on the foot (n=25)



Mean plantar pressures at various points on the foot

We compared plantar pressure points during gait in the precious limb while using axillary crutches or walkers (without prosthesis) and while using prosthesis. The plantar pressures were measured in Kilopascals (kPa). The following differences were observed. **(Fig. 13-17)**

Fig. 13 : Comparing mean pressure (kPa) at hallux with and without prosthesis

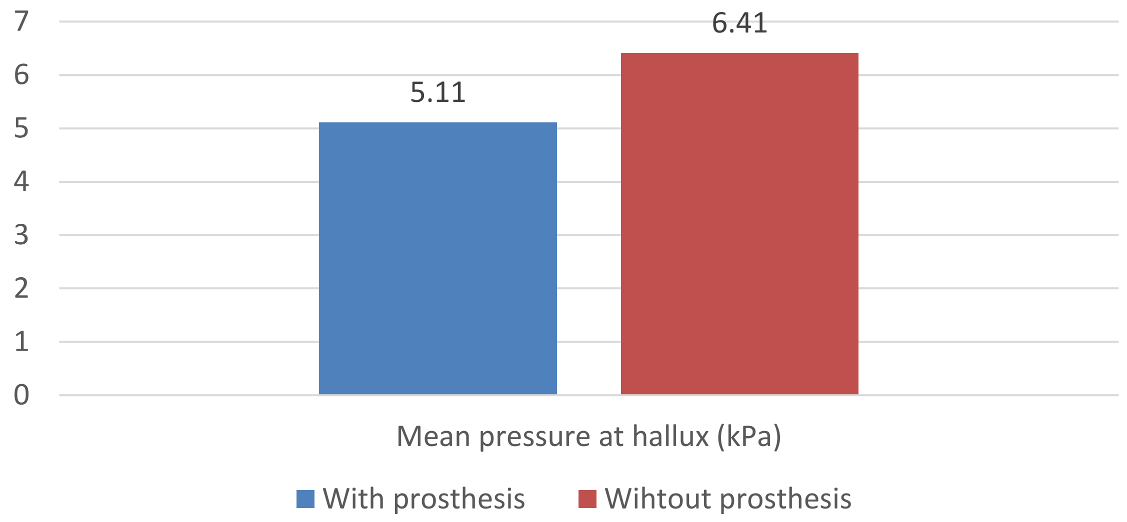
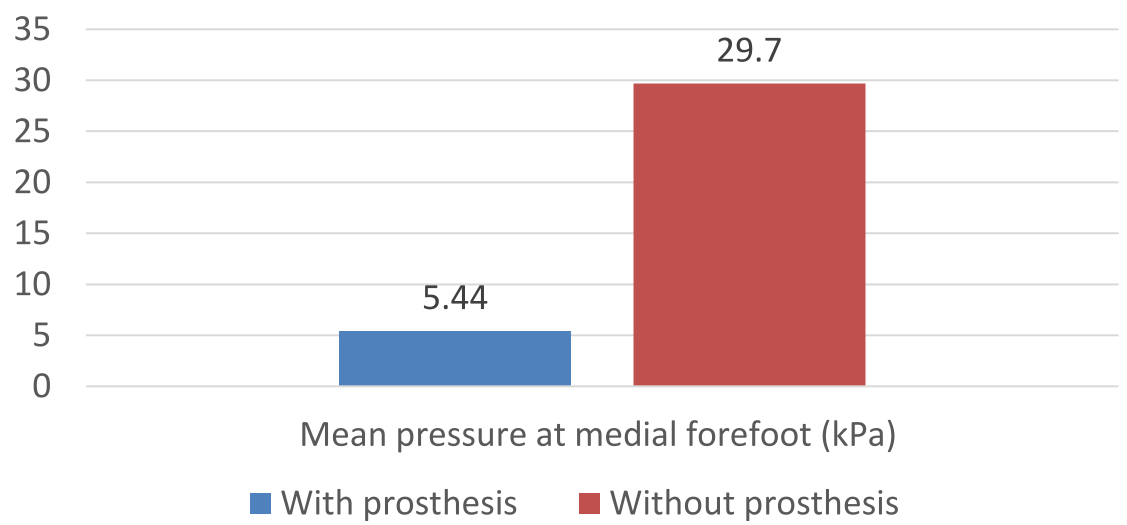


Fig. 14: Comparing mean pressure (kPa) at medial forefoot with and without prosthesis



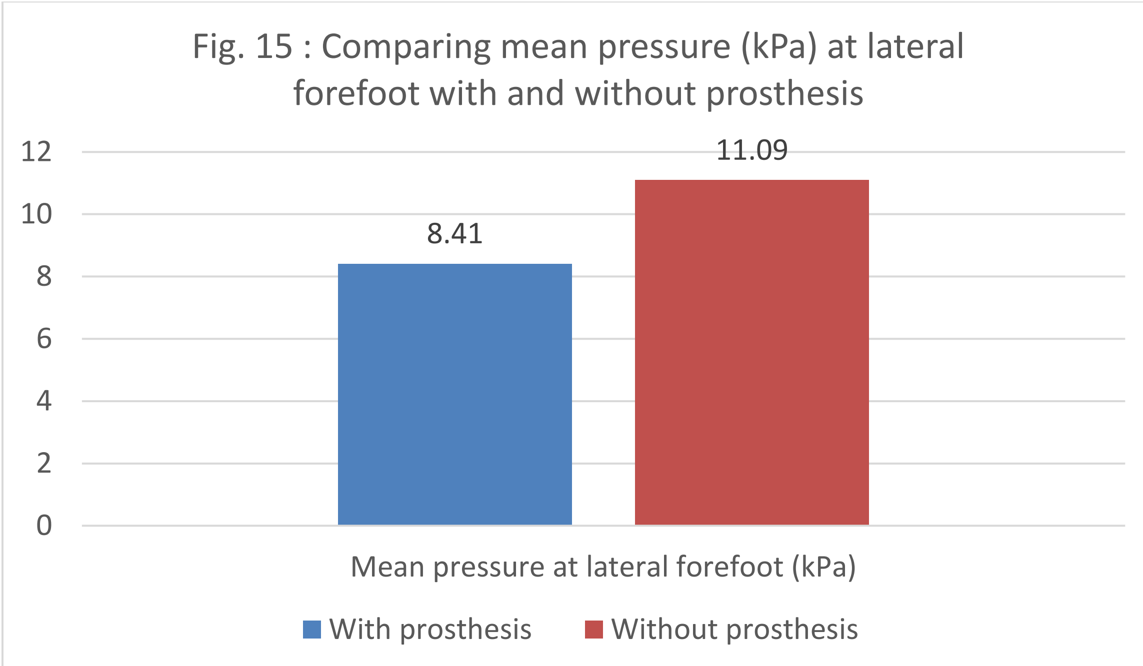


Fig. 15 : Comparing mean pressure (kPa) at lateral forefoot with and without prosthesis
12
10
8
6
4
2
0
11.09
8.41
Mean pressure at lateral forefoot (kPa)
With prosthesis
Without prosthesis

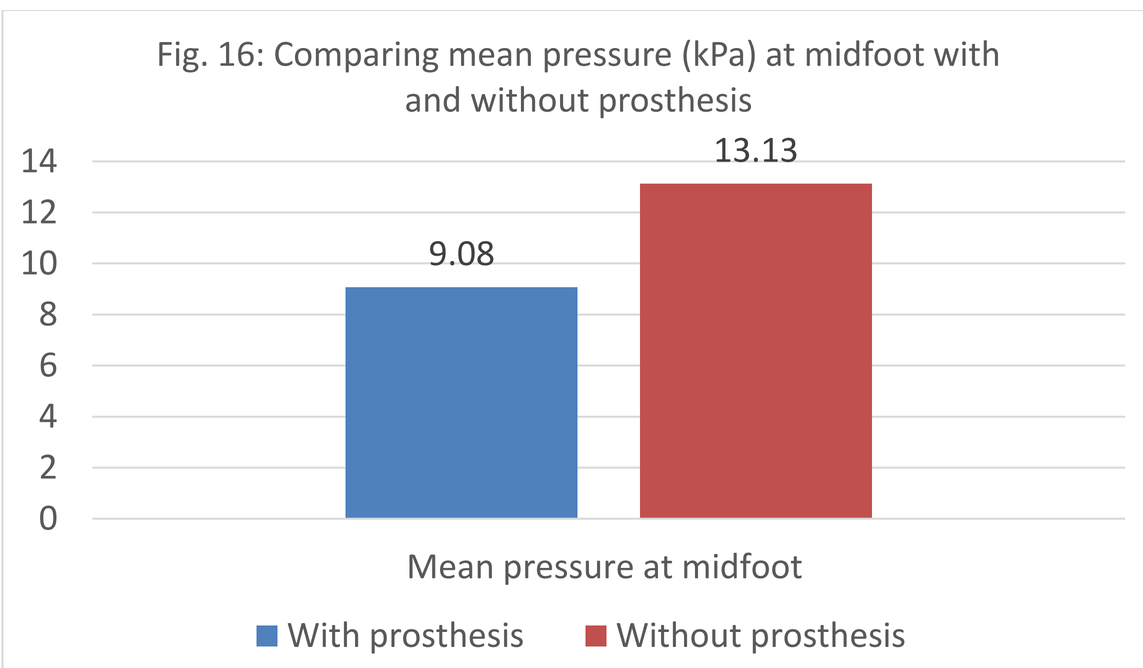
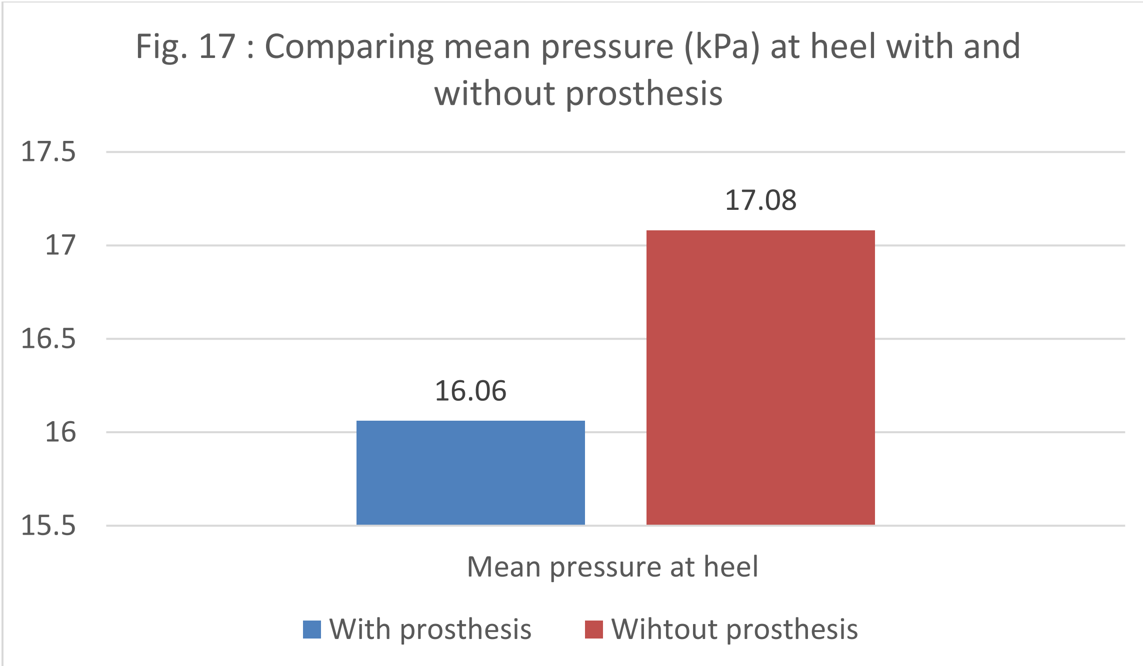


Fig. 16: Comparing mean pressure (kPa) at midfoot with and without prosthesis
14
12
10
8
6
4
2
0
13.13
9.08
Mean pressure at midfoot
With prosthesis
Without prosthesis



A significant difference was observed between the various plantar pressure points during gait with and without a prosthesis. **(Table 1)**

There were significant differences in pressures at the medial forefoot, lateral forefoot, and midfoot. Though the pressures were lower over the hallux and the heel in the group with prosthesis, this was not statistically significant.

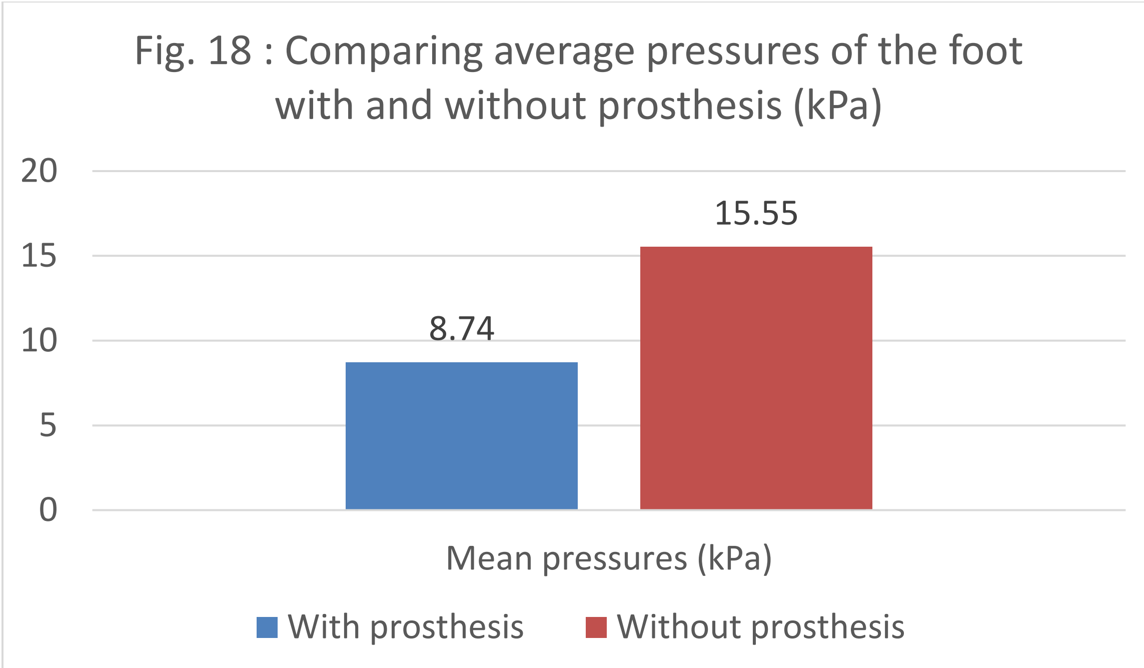
TABLE 1: COMPARISON OF PRESSURES AT 5 DESIGNATED POINTS ON THE SOLE WITH AND WITHOUT PROSTHESIS

	With prosthesis			Without prosthesis			
	Mean (kPa)	**S. D**	**Median (kPa)**	**Mean (kPa)**	**S. D**	**Median (kPa)**	**p value**
HALLUX	5.11	4.13	3.70	6.41	7.09	4.10	0.097
MED. FOREFOOT	5.44	6.37	3.60	29.78	96.34	5.50	0.001
LATERAL FOREFOOT	8.41	8.34	6.40	11.09	10.37	8.10	0.028
MIDFOOT	9.08	8.19	6.10	13.13	9.76	9.10	0.005
HEEL	16.06	14.33	11.70	17.08	15.25	16.60	0.637

We compared the average median pressure for each foot which showed significant difference **(Fig. 18, Table 2**; Wilcoxon signed ranks test**, p <0.001**)

TABLE 2: COMPARISON OF AVERAGE MEDIAN PRESSURES OF THE FOOT WITH AND WITHOUT PROSTHESIS

	WITH PROSTHESIS (kPa)	**WITHOUT PROSTHESIS (kPa)**	**p value**
MEAN	8.74	15.55	**<0.001**
STD DEVIATION	4.518	18.916	
MEDIAN	7.76	9.98	



Forefoot to rear-foot ratio:

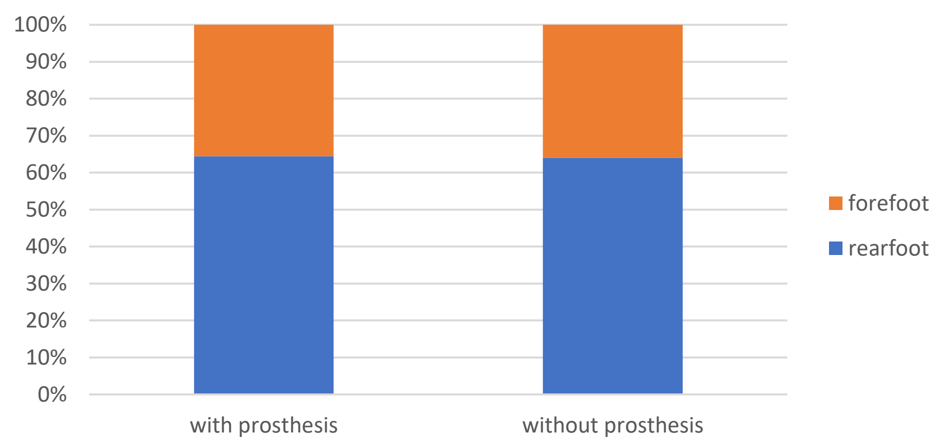
Forefoot pressures were separately compared to the rearfoot. The forefoot pressure was averaged from pressures over the hallux, medial and lateral forefoot and the rear foot pressure was averaged from the midfoot and heel pressures.

We compared forefoot to rearfoot pressures and found that the forefoot to rear-foot pressures ratio was lower with prosthesis due to higher pressures in the rear-foot. The mean pressures in the rear-foot was found to be 12.57 kilopascals with prosthesis as compared to mean pressures of 15.1 kilopascals without a prosthesis. There was consistent reduction in forefoot and rearfoot pressures in the group that used prosthesis and the ratio of these pressures (when comparing the median pressures) was similar. **(Table 3, Fig. 19)**

TABLE 3: COMPARISON OF FOREFOOT AND REARFOOT PRESSURES

	WITH PROSTHESIS		WITHOUT PROSTHESIS	
	Forefoot	**Rear-foot**	**Forefoot**	**Rear-foot**
MEAN	6.32	12.57	15.76	15.11
STANDARD DEVIATION	4.12	7.88	31.7	8.85
MEDIAN	5.4	9.8	7.6	13.5
% OF TOTAL PLANTAR PRESSURE	35.5%	64.5%	36%	64%

Fig. 19 : Percent contribution of forefoot and rearfoot to total plantar pressures



Correlation of Body Mass Index (BMI) and prosthetic use

For the 25 patients assessed, the average BMI of the patients was found to be 24.63 kg/cm^{2}.

There was no significant correlation seen between Body Mass Index and plantar pressures with or without prosthesis. **(Fig.20,21; Table 4)**

Table 4: Correlation of BMI and plantar pressures

Prosthesis			BMI	Average foot pressure
yes	BMI	Pearson Correlation	1	.197
		Sig. (2-tailed)		.346
		N	25	25
	Average plantar pressure	Pearson Correlation	.197	1
		Sig. (2-tailed)	.346	
		N	25	25
no	BMI	Pearson Correlation	1	-.333
		Sig. (2-tailed)		.104
		N	25	25
	Average plantar pressure	Pearson Correlation	-.333	1
		Sig. (2-tailed)	.104	
		N	25	25

Fig. 20 : Scatter plot of BMI and plantar pressure in group with prosthesis

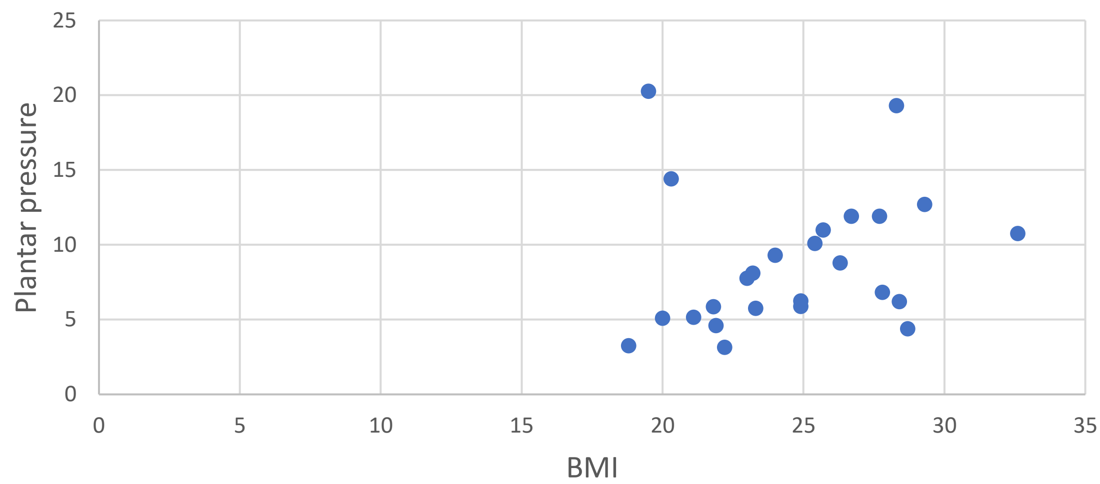
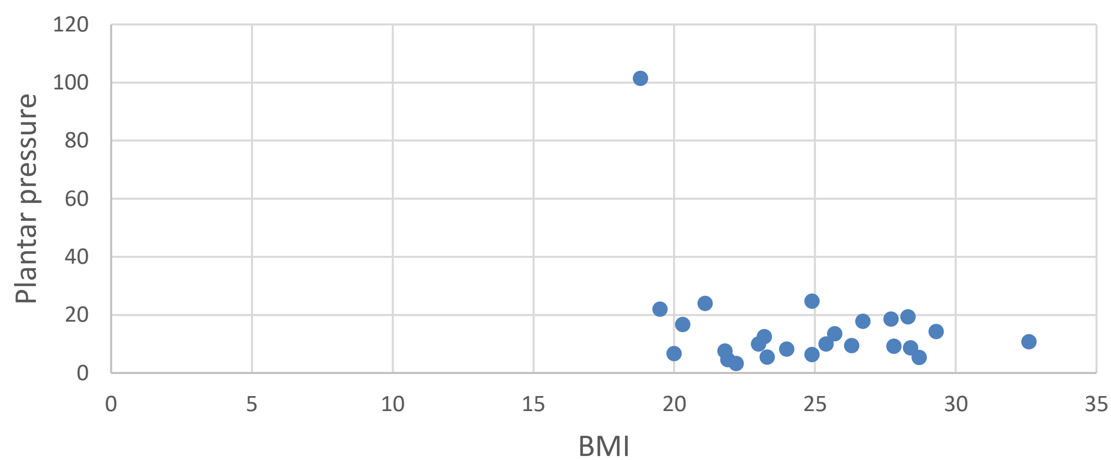


Fig. 21: Scatter plot of BMI and plantar pressures in group without prosthesis



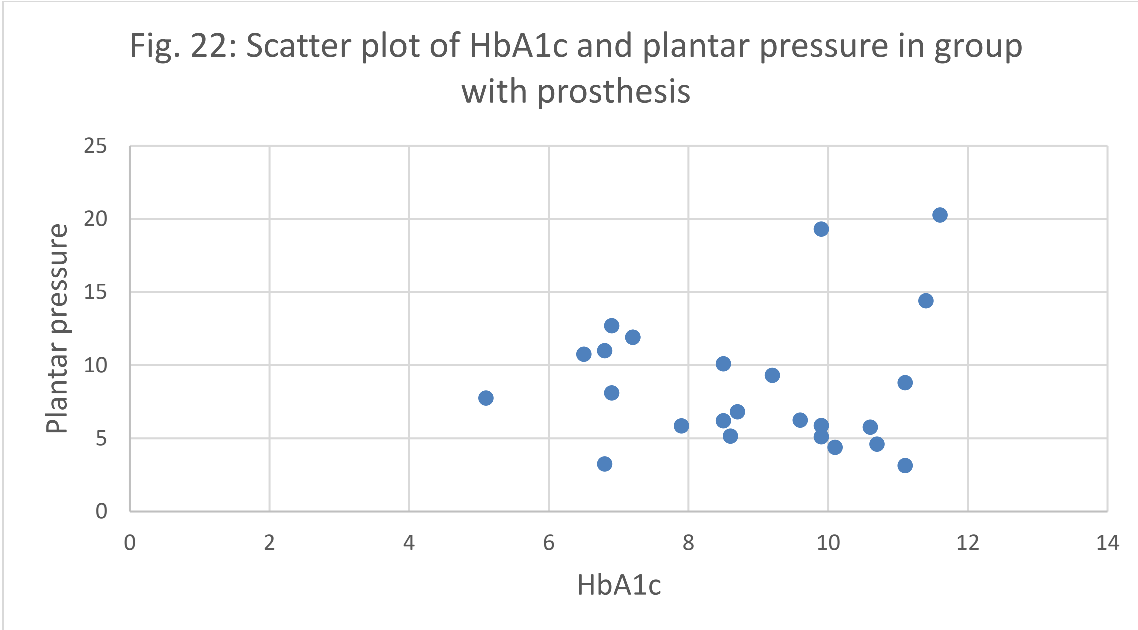
Hence Body Mass Index did not have any effect on plantar pressure changes with or without prosthesis.

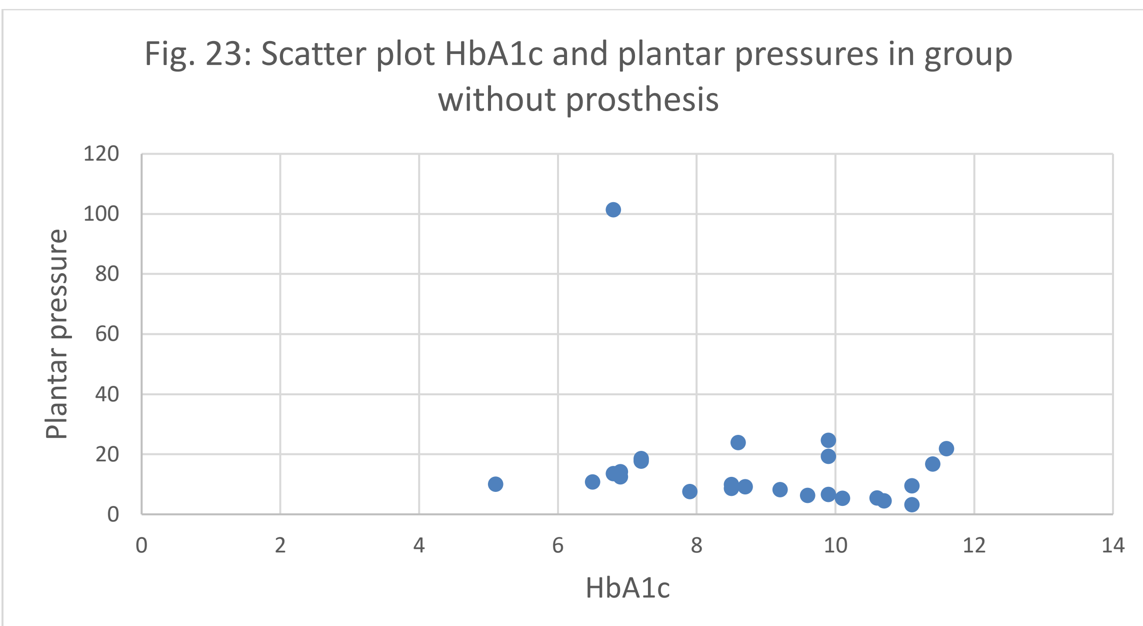
Correlation of Glycosylated Hemoglobin (HbA1c) with plantar pressures with or without prosthesis

The average HbA1c for these 25 patients was found to be 8.8%. There was no correlation seen between HbA1c and prosthetic usage and its effect on plantar pressures. **(Fig. 22, 23; Table 5)**

Table 5: Correlation of HbA1c and plantar pressures

Prosthesis			Average foot pressure	HBA1C
yes	Average foot pressure	Pearson Correlation	1	.055
		Sig. (2-tailed)		.792
		N	25	25
	HBA1C	Pearson Correlation	.055	1
		Sig. (2-tailed)	.792	
		N	25	25
no	Average foot pressure	Pearson Correlation	1	-.251
		Sig. (2-tailed)		.226
		N	25	25
	HBA1C	Pearson Correlation	-.251	1
		Sig. (2-tailed)	.226	
		N	25	25





Hence, no statistical significance was seen.

Duration of rehabilitation

The duration of rehabilitation, that is, the time since amputation till when the patient first started using prosthesis, was as follows:

Statistics

duration_rehab_months

N	Valid	25
	Missing	0
Mean		15.5600
Median		8.0000
Std. Deviation		18.96506
Minimum		4.00
Maximum		88.00

Hence, mean number of months to rehabilitation was 15 months since the time of amputation in our study group.

DISCUSSION

The primary objective of this study was to compare the plantar pressure points during ambulation with a prosthesis and without a prosthesis using crutches or walkers in diabetic patients who have undergone a trans-tibial amputation and have been rehabilitated. The dynamic plantar pressures on the precious limb were found to be significantly lower with prosthesis during gait as compared to crutches or walkers. The difference in dynamic plantar pressures with and without prosthesis was found to be the highest at the head of the first metatarsal in our study. This was in accordance to earlier studies done by D.V.Rai et al who found highest forefoot pressures located under the second and third metatarsal heads. The pressure difference can also be explained in accordance with the gait cycle. While using orthotic devices, the plantar aspect of the precious limb lands with maximum weight bearing over the metatarsal heads as the foot prepares for the next lift-off of the gait cycle, thereby causing maximum pressures in those areas. As compared to this, while using prosthesis, after proper prosthetic training, a uniform distribution of pressures occurs over all the five plantar points, as the patient now attempts to resume a normal gait, relying less on the upper limbs used in orthotics, and more on the amputated limb, with the stump resting on the prosthetic socket.

In our patients, there was no significant relation seen between the pressures on the precious limb and the weight of the patient or Body Mass Index (BMI) or the patient's glycemic control at the time of the surgery. There were no statistically significant correlations of these parameters to pressures with or without prosthesis.

Sensory distribution and loss of sensation showed a wide range of variation with plantar pressure differences and were statistically insignificant.

The study suggests that, during gait, an amputee who has been rehabilitated with a prosthetic and has received proper prosthetic training will have significantly lower plantar pressures as compared to those who continue to use crutches or walkers. While orthotics provide uniformity in the distribution of plantar pressures during bipedal standing, during gait, it will be a less effective modality as compared to a prosthesis in reducing plantar pressures.

The study also suggests that pressure distribution measurement techniques are useful in understanding the biomechanics of the foot during gait. In diabetic amputees, this is of utmost importance, as it can be used as a diagnostic and therapeutic tool in detecting early pressure changes, and aid in timely intervention, in the form of footwear or prosthetic modification, to reduce pressures. The end point being, that ulcer formation, infection and subsequent amputation is prevented in the precious limb.

CONCLUSION

The dynamic plantar pressures were lower with prosthesis as compared to without prosthesis. The mean pressure difference was found to be about 6.8 kiloPascals. ($p < 0.001$)

The highest pressure difference amongst individual plantar points was found to be at the first metatarsal, with a mean difference of 24.3 kiloPascals. ($p < 0.001$)

The forefoot to rear-foot ratio was not found to be significant. Body Mass Index and glycemic control did not contribute to pressure changes during gait while using prosthesis.

Hence this proves our hypothesis, that prosthesis is more effective in reduction of plantar pressures in the precious limb in Diabetics during gait, as compared to orthotic devices like crutches or walkers. Hence, it is recommended that Diabetic amputees be encouraged to undergo pre-prosthetic training and eventually use prosthesis for ambulation.

Also, even though the patient may have been rehabilitated with a prosthesis, it is imperative that regular inspection of the precious foot is done. This said, the device can be used as a standard, economic, diagnostic and therapeutic tool in detecting early pressure changes and that plantar pressure distribution become a routine part during diabetic foot assessment.

LIMITATIONS

In this study, we have only looked at the plantar pressures as one of the decisive factors for subsequent ulcer formation and contralateral amputation in Diabetic patients. Various other factors, like vascularity and tissue oxygenation also play an important role in ulcer formation in the Diabetic foot. These will be taken into consideration in further studies in the future.

The device, used for plantar pressure measurement, is an in-house device, and not a standardized tool for measuring pressures and is subject to wear and tear of the pressure sensing probes.

Also, long term follow up of these patients is essential.

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ANNEXURES

Proforma – Data collection:

Name: _________________________ Age:_____ Gender:____ Patient ID No.______

Date of Surgery: Operation: ____________________________________

Date of assessment:

HbA1c: _____% ( ) Wt________ Ht__________ BMI_________

Sensory assessment: Fine touch 1gm □ 10gm □ Absent □ Hallux □ Med. Forefoot □

Lat.Forefoot □ Midfoot □

Heel □

With prosthesis:

	1	2	3	4	5	6	7	8	9	10	Mean
probe 1											
probe 2											
Probe 3											
Probe 4											
Probe 5											

Without prosthesis:

	1	2	3	4	5	6	7	8	9	10	Mean
Probe 1											
probe 2											
Probe 3											
Probe 4											
Probe 5											

Mean pressure:

With prosthesis ______

Without prosthesis ______

CONSENT FOR PARTICIPATION

Study Title: *An observational study to study the plantar pressure changes in the contralateral limb in Diabetic patients who have undergone a below knee amputation while using axillary crutches/walkers and while using a prosthesis.*

ID no. :

Participant's name:

Age:

I____

____son/daughter of____

(Please tick boxes)

Declare that I have read the information sheet provided to me regarding this study and have clarified any doubts that I had [ ]

I also understand that my participation in this study is entirely voluntary and that I am free to withdraw permission to continue to participate at any time without affecting my usual treatment or my legal rights [ ]

I understand that I will receive free treatment for any study-related injury or adverse event but I will not receive any form of financial compensation [ ]

I understand that the study staff and Institutional Ethics Committee members will not need my permission to look at my health records even if I withdraw from the trial. I agree to this access [ ]

I understand that my identity will not be revealed in any information released to the third parties or published [ ]

I voluntarily agree to take part in this study [ ]

Name :	**Name of witness:**
Signature :	**Relation to participant:**
Date :	**Date:**

INFORMED CONSENT

Christian Medical College Vellore

Department of General Surgery

An observational study to study characteristics of plantar pressure distribution in diabetic patients in the contralateral limb who have undergone an amputation after being rehabilitated with prosthesis and crutches/walkers

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You are being requested to participate in a study to determine plantar pressures in your normal limb following amputation in the other limb and compare these pressures while walking with a prosthesis and while walking with a crutch or walker. You have recently undergone a lower limb amputation following a diabetic foot ulcer. There is a 5-11% chance of you having to undergo another amputation of the normal limb over the next four years. This study is designed to identify that risk and prevent subsequent amputation.

What is the purpose of the study?

Diabetes accounts for a majority of lower limb amputations in the adult population. Once the patient undergoes either a major or minor amputation, the centre of gravity of the patient automatically shifts to the contralateral lower limb. Due to this reason, it is imperative to protect that limb from plantar ulcer formation. After a major amputation, it was found that 5.7% and 11.5% people have a contralateral major amputation at 1and 5 years respectively. The main aim of this study is to prevent this bilateral limb loss in patients with Diabetes Mellitus.

What is the relation between Diabetic foot amputations and prosthetic devices or walkers and crutches?

It has been shown that the use of prosthetic devices not only protects the limb that has undergone some form of amputation, but also redistributes plantar pressure of the other limb to prevent ulcer formation over the precious foot and avoid another amputation.

If you take part what will you have to do?

If you agree to participate in this study, you will be asked a few questions about your age, duration of Diabetes and the last time your sugars were checked. We will also be checking your feet for signs of nerve damage along with the plantar pressure assessment of the precious foot while walking with crutches or walkers. This will be conducted when you will be coming for your training with your prosthesis. After three months, this procedure will be repeated, this time measuring foot pressures while walking with the prosthesis only. We will also be collecting a single blood sample using standard precautions to measure glycosylated blood sugar levels. We will also be collecting information regarding previously conducted blood tests in the hospital from the medical records system.

All other treatment that you are already on will be continued and your regular treatment will not be changed during this study. No additional blood tests or procedures will be conducted during this study.

Can you withdraw from this study after it starts?

Your participation in this study is entirely voluntary and you are also free to decide to withdraw permission to participate in this study. If you do so, this will not affect your usual treatment in the hospital in any way.

What will happen if you develop any study related injury?

We do not expect any injury to happen to you, but if you do develop any side effects or problems due to the study, these will be treated at no cost to you. We are unable to provide any monetary compensation, however.

Will you have to pay for the blood tests?

The blood test taken from you for the purpose of this study will be done free of cost.

Will your personal details be kept confidential?

The results of this study will be published in a medical journal but you will not be identified by name in any publication or presentation of results. However, your medical notes may be reviewed by people associated with the study, without your additional permission, should you decide to participate in this study.

If you have any further questions, please ask Dr. JALAZ JOEZER RAHMI (tel. 04162282082/ +91 8527017075) or email jalaz_rahmi@yahoo.co.in

slno	name	age	sex	patid	dos	operat	doa	hba1c
1	Dharman Paneer	64	MALE	996811D	21/12/2016	Left	22/042017	6.8
2	Munusamy A	55	MALE	548868G	04/04/2017	Left	31/08/2017	11.4
3	Elango K.	63	MALE	840043G	15/04/2017	Left	09/01/2018	8.6
4	Abul Kalam Azad	65	MALE	851392G	01/03/2016	Left	11/05/2017	9.6
5	Munirathinam V.	65	MALE	371402D	28/02/2017	Right	25/08/2017	10.6
6	Anburaj	60	MALE	406132F	18/02/2013	Left	13/06/2017	7.9
7	Guna Devi	48	FEMALE	318707B	26/01/2017	Left	20/09/2017	10.7
8	Venkatesan	60	MALE	503320G	17/04/2016	Left	27/06/2018	9.2
9	Balakrishna Naidu	57	MALE	515597F	02/09/2015	Right	08/04/2018	9.9
10	Nathi Devi Mali	50	FEMALE	284259G	01/01/2017	Left	28/08/2017	8.7
11	Bhagyalakshmi	35	FEMALE	935184G	04/09/2017	Right	18/04/2018	11.6
12	Selvaraj	61	MALE	936040G	12/09/2017	Right	27/06/2018	6.5
13	Vijaykumar	52	MALE	948878F	14/09/2017	Right	31/05/2018	11.1
14	Srinivasan A	53	MALE	482692G	18/09/2017	Left	15/04/2018	10.1
15	Samuel A.	67	MALE	885997A	19/12/2017	Right	05/05/2018	5.1
16	Veeramani V.	54	MALE	585387G	14/12/2017	Left	04/05/2018	8.5
17	Arumugam	57	MALE	938501G	03/10/2017	Right	16/03/2018	9.9
18	Raja	53	MALE	990562F	31/03/2016	Right	04/05/2018	7.2
19	Rajunathu Singh	54	MALE	586442G	21/01/2018	Left	31/05/2018	6.9
20	Sagunthala R.	70	FEMALE	213458F	03/01/2011	Left	31/05/2018	6.9
21	Dhanapal	66	MALE	429799G	21/01/2016	Right	26/06/2018	6.8
22	Udhaya Kumar	47	MALE	547642G	26/03/2017	Right	27/06/2018	7.2
23	Sourimuthu	71	MALE	162920A	16/05/2017	Left	02/07/2018	9.9
24	Dilip Kumar Ghosh	56	MALE	990277G	19/09/2017	Right	25/07/2018	11.1
25	Purushottamman T.R.	80	MALE	553460a	14/03/2018	Right	16/08/2018	8.5

wt	ht	bmi	hallux	medfore	latfore	midfoot	heel	halluxwp	medwp	latwp
48	160	18.8	Present	Absent	present	present	present	2.3	2.3	0.6
60	172	20.3	Present	present	present	present	present	2.7	15.5	2.1
54	160	21.1	Present	present	present	present	present	2.3	7	9.5
72	170	24.9	Present	present	present	Absent	Absent	2.6	3.09	2
65	167	23.3	Present	present	present	present	present	10.5	4	1.7
64.6	172	21.8	Present	present	present	present	present	5.1	4.4	1.8
52	154	21.9	Present	present	present	present	present	6.7	3.8	1.8
76	178	24	Absent	present	Absent	Absent	present	2.3	3.6	13.6
72	170	24.9	Present	present	present	present	present	4	4.8	5.2
66	154	27.8	Present	present	present	present	present	5	7	1.9
45	152	19.5	Present	present	present	present	present	10.6	3	38
92	168	32.6	Absent	present	present	present	present	2.3	2.3	6
54	156	22.2	Present	present	present	present	present	3.1	0.3	6.4
78	165	28.7	Present	present	present	present	present	4.3	0.9	5.7
68	172	23	Present	present	present	present	present	7.5	4.9	6.7
65	160	25.4	Present	present	present	present	present	5.5	21	6.8
80	168	28.3	Present	present	Absent	present	Absent	7.1	26.5	21.6
80	170	27.7	Present	present	present	present	Absent	3.1	5.2	10.9
75	160	29.3	Present	present	present	present	present	4.5	0.7	20.39
55	154	23.2	Present	present	present	present	present	21.3	1.5	8
70	165	25.7	Absent	Absent	Absent	present	present	3.4	2.1	3.5
70	162	26.7	Present	present	present	present	present	2.8	7.1	6.9
50	158	20	Present	present	present	present	present	2.3	0.3	16
76	170	26.3	Present	present	present	present	present	2.8	2.5	5.6
82	170	28.4	Present	present	present	present	present	3.7	2.4	7.8

midwp	heelwp	halluxwop	medwop	latwop	midwop	heelwop	withpros	withoutprs
1.1	10	2.8	490	2.8	10	1.7	3.26	101.4
20.7	31	3	19.5	2.4	28.2	30.7	14.4	16.7
4.3	2.7	4.2	15.8	31.4	7	61.3	5.16	23.9
20	3.54	3	7	1.5	19	1.09	6.24	6.31
8.8	3.8	2.7	1.9	1.8	9.1	11.4	5.76	5.38
3.8	14.2	5.3	4.6	1.9	6.6	19.2	5.86	7.52
5	5.7	5.1	4.2	2.2	6	5.3	4.6	4.5
5.2	21.8	2.3	5.4	11.8	4.7	17.2	9.3	8.2
4.9	10.5	5.08	27.9	26.5	28.4	35.4	5.88	24.65
13	7.2	5.2	11.4	2	19.8	7.2	6.82	9.12
5.8	52	8.2	2.7	41	6.8	42.6	20.26	21.88
8.9	34.3	2.4	2.9	7.3	10.5	30.6	10.76	10.7
3.9	2	4.1	2.6	3.9	2.6	1.7	3.14	3.2
6.1	4.9	4.6	0.6	7.2	7.4	6.7	4.38	5.3
3.7	16	8.3	5.3	9.2	6.5	20.6	7.76	9.98
5.7	11.7	3.8	5.5	15.7	7.8	16.6	10.1	9.9
41.4	0.17	7.1	29	22	34.6	3.9	19.3	19.3
10.5	30	3.2	19.5	20.7	35.8	13.3	11.9	18.5
9	29	28	26.3	8.1	5.2	3.6	12.7	14.2
8.7	0.7	30	2.5	12	17.2	0.6	8.1	12.46
8.4	37.9	9.8	17.9	3	8.5	27.9	11	13.5
11.1	31.9	3.5	28.2	12.6	21.2	23.2	11.9	17.7
6.9	0.1	2.4	3.1	16.9	10.3	0.4	5.1	6.6
5.9	27.3	3.1	4.3	8.2	12.4	19.1	8.8	9.42
4.2	13.1	3.2	6.5	5.2	2.7	25.8	6.2	8.6